PCT WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 : A61F 2/06

A1

(11) International Publication Number: **WO 99/65418**

(43) International Publication Date: 23 December 1999 (23.12.99)

(21) International Application Number: PCT/GB98/00867

(22) International Filing Date: 3 April 1998 (03.04.98)

(30) Priority Data:
9706766.4 3 April 1997 (03.04.97) GB

(71) Applicant *(for all designated States except US)*: SULZER VASCUTEK LIMITED [GB/GB]; Newmains Avenue, Inchinnan, Renfrewshire PA4 9RR (GB).

(72) Inventors; and
(75) Inventors/Applicants *(for US only)*: ASHTON, Timothy, Rawden [GB/GB]; 20 Yerton Brae, West Kilbride (GB). STEVENSON, David, Granville [GB/GB]; 4B Blairbeth Terrace, Burnside, Glasgow G73 4JB (GB).

(74) Agent: MURGITROYD & COMPANY; Chartered Patent Agents, 373 Scotland Street, Glasgow G5 8QA (GB).

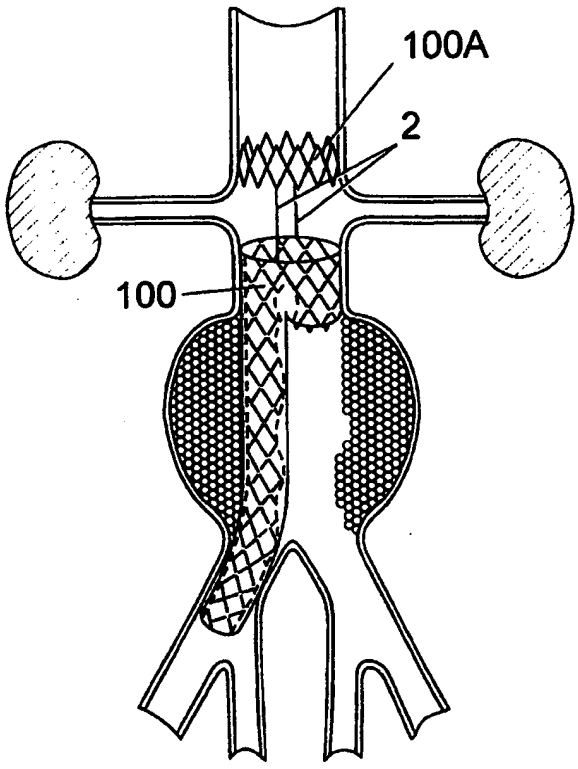
(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, GM, GW, HU, ID, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).

Published
With international search report.

(54) Title: ENDOVASCULAR PROSTHESES, AN INTRODUCER AND SURGICAL PACKAGE THEREFOR AND HAEMOSTATIC VALVE

(57) Abstract

There is provided an endovascular prosthesis suitable for an aortic aneurysm, especially in the renal aorta. The prosthesis includes a separate anchor stent separated from the main stent by at least one linking strut or wire. Usually 2, 3 or 4 linking struts or wires will be present. The stents are desirably formed from a shape memory alloy such as nitinol. The main stent may be covered with a suitable fabric or membrane, but the anchor stent is preferably unclad. An introducer, with a facility to deploy the anchor stent after correct positioning of the main stent, is also described. A haemostatic valve comprising an elastomeric sleeve, which is preferably pinched off by rotation of one end, is further described.



FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	**ES**	Spain	**LS**	Lesotho	**SI**	Slovenia
AM	Armenia	**FI**	Finland	**LT**	Lithuania	**SK**	Slovakia
AT	Austria	**FR**	France	**LU**	Luxembourg	**SN**	Senegal
AU	Australia	**GA**	Gabon	**LV**	Latvia	**SZ**	Swaziland
AZ	Azerbaijan	**GB**	United Kingdom	**MC**	Monaco	**TD**	Chad
BA	Bosnia and Herzegovina	**GE**	Georgia	**MD**	Republic of Moldova	**TG**	Togo
BB	Barbados	**GH**	Ghana	**MG**	Madagascar	**TJ**	Tajikistan
BE	Belgium	**GN**	Guinea	**MK**	The former Yugoslav Republic of Macedonia	**TM**	Turkmenistan
BF	Burkina Faso	**GR**	Greece			**TR**	Turkey
BG	Bulgaria	**HU**	Hungary	**ML**	Mali	**TT**	Trinidad and Tobago
BJ	Benin	**IE**	Ireland	**MN**	Mongolia	**UA**	Ukraine
BR	Brazil	**IL**	Israel	**MR**	Mauritania	**UG**	Uganda
BY	Belarus	**IS**	Iceland	**MW**	Malawi	**US**	United States of America
CA	Canada	**IT**	Italy	**MX**	Mexico	**UZ**	Uzbekistan
CF	Central African Republic	**JP**	Japan	**NE**	Niger	**VN**	Viet Nam
CG	Congo	**KE**	Kenya	**NL**	Netherlands	**YU**	Yugoslavia
CH	Switzerland	**KG**	Kyrgyzstan	**NO**	Norway	**ZW**	Zimbabwe
CI	Côte d'Ivoire	**KP**	Democratic People's Republic of Korea	**NZ**	New Zealand		
CM	Cameroon			**PL**	Poland		
CN	China	**KR**	Republic of Korea	**PT**	Portugal		
CU	Cuba	**KZ**	Kazakstan	**RO**	Romania		
CZ	Czech Republic	**LC**	Saint Lucia	**RU**	Russian Federation		
DE	Germany	**LI**	Liechtenstein	**SD**	Sudan		
DK	Denmark	**LK**	Sri Lanka	**SE**	Sweden		
EE	Estonia	**LR**	Liberia	**SG**	Singapore		

"Endovascular Prostheses, an introducer and surgical package therefor and haemostatic valve"

This invention relates to endovascular protheses, and relates more particularly but not exclusively to stents for aortic aneurysms in humans and other mammals.

It has been proposed that an aneurysm in the aorta should be treated by insertion therein of an endovascular stent covered by a sheath of fabric which is substantially impermeable to blood. The stent is introduced into the artery in a radially collapsed state, displaced to overlap the aneurysm, and then allowed to expand radially such that it self-anchors on the arterial wall on either side of the aneurysm. This decreases the pressure on the weakened walls of the aneurysm, preventing further weakening thereof and decreasing the possibility of rupture. Although better anchorage of the stent could be obtained by anchoring the upper end of the stent in the aorta above the renal arteries, the fabric covering of the stent would block renal blood flow, with unacceptable consequences for the health of the patient. However, omitting the fabric from a supra-renally anchored stent allows the anchoring stent to be placed above the renal arteries

while maintaining renal perfusion.

According to a first aspect of the present invention there is provided an endovascular prosthesis for a vascular aneurysm, the prosthesis comprising a tubular membrane means which is substantially impermeable to blood and which is disposable to convey blood between substantially non-aneurysmal regions on either side of the aneurysm, the prosthesis further comprising selectively deployable anchor means for anchoring in the vascular wall at an anchoring location displaced from the aneurysm, the anchor means being linked to the tubular membrane means by link means comprised in the prosthesis, the link means being such as to cause minimal turbulence in side-branching blood vessels branching from a point between the aneurysm and the anchoring location.

The anchor means preferably comprises an expandable metal mesh annular stent which is preferably unclad by any membrane or fabric.

The link means preferably comprises at least one longitudinally extending strut or wire. Preferably the link means comprises 2, 3 or 4 separate struts or wires which may be spaced equidistantly.

The tubular membrane means preferably comprises a sleeve of a fabric which is preferably a fabric as described in an International Patent Application No PCT/GB97/02071 located over an expandable metal mesh tubular stent which is in a radially collapsed form for emplacement of the prosthesis and which is expandable when located to shunt the aneurysm.

The stents comprised in the anchor means and in the

tubular membrane means are preferably formed of a shape memory alloy which may be an alloy comprising nickel and titanium, for example nitinol.

According to a second aspect of the present invention there is provided an introducer for endovascular emplacement of an endovascular prosthesis according to the first aspect of the present invention, the introducer comprising a flexible tubular guide means externally dimensioned for passage along a vascular duct from an extracorporeal location to the site of the aneurysm and to the anchoring location, the guide means being internally dimensioned to encompass the prosthesis in its initially radially collapsed state without preventing controlled longitudinal displacement of the prosthesis relative to the guide means during emplacement of the prosthesis, the introducer further comprising a hollow capsule for containing the anchor means in an initially radially collapsed state, one end of the capsule being detached from the remainder of the capsule and inserted inside the remainder of the capsule to lie within or adjacent the other end of the capsule such as to leave the remainder of the capsule between said inserted one end and the other end of the capsule for containing the collapsed anchor means, the introducer additionally comprising displacement control means for longitudinally displacing the capsule with respect to the tubular guide means, the introducer further comprising capsule end replacement means for replacing said one end of the capsule following deployment of the anchor means whereby to facilitate withdrawal of the capsule following emplacement of the prosthesis.

The capsule end replacement means may comprise spring means disposed within the capsule between the opposite

ends thereof to urge the detached end of the capsule towards its replaced position. Alternatively, the capsule end replacement means may comprise Bowden cable means having a core wire threaded through the longitudinal axis of the introducer as a guide wire for the introducer, and having a Bowden sheath coupled to the detached end of the capsule, the Bowden sheath preferably functioning as the displacement control means.

According to a third aspect of the present invention, there is provided a surgical package comprising the operative combination of an endovascular prosthesis according to the first aspect of the present invention and an introducer according to the second aspect of the present invention, the tubular membrane means of the prosthesis being in an initially radially collapsed configuration and located within the tubular guide means, the anchor means of the prosthesis being in an initially radially collapsed configuration and located with the capsule, the anchor means being linked to the tubular membrane means by the link means such that the anchor-encompassing capsule is also linked to the tubular membrane means, the capsule being disposed at the leading end of the tubular guide means, the displacement control means being threaded through the tubular guide means and through the tubular membrane means.

The displacement control means preferably extends through the end of the tubular guide means remote from the end of the guide means initially holding the prosthesis for extracorporeal control of the displacement of the capsule.

According to a fourth aspect of the present invention

there is provided a haemostatic valve, optionally for use with the surgical package according to the third aspect of the present invention, the haemostatic valve comprising an elastomeric sleeve, a first end of the sleeve being sealed to a first sealing means, a second end of the sleeve being sealed to a second sealing means, and pinch control means for controllably pinching the sleeve where it extends between the two sealing means whereby controllably to seal around the tubular guide means or the displacement control means as it passes through the sleeve. One side of the valve will be sealed to the introducer in a blood tight manner. Optionally, the valve may comprise a coupling means to allow connection and disconnection to the introducer.

The pinch control means may comprise pressurisation means for externally pressurising the sleeve means to pinch the sleeve onto whichever article is currently extending through the sleeve. Alternatively, the pinch control means may comprise rotation control means for controllably inducing relative rotation of the first and second sealing means about a common axis such as to twist the sleeve about its longitudinal axis where it extends between the two sealing means whereby to collapse the sleeve onto whichever article is currently extending through the sleeve. The rotation control means preferably comprises bearing means rotationally coupling the two sealing means for relative rotation about a common axis, spring means acting between the two sealing means to bias them into relative rotation in a sense tending to induce rotational collapse of the sleeve, and manually engageable means attached to or forming part of the sealing means by which the bias of the spring means may be controllably counteracted by the application of manual force such as controllably to

open the valve by a selected amount.

The present invention further provides a stent formed from a mesh characterised in that said mesh comprises a linking element wherein each end of said element is connected at a connecting point to the mesh and wherein the length of said element exceeds the distance between the connecting points. In one embodiment the linking element comprises an "S"-shaped bend and optionally the linking element itself may be substantially in the form of an "S"-shape. It is an important part of the present invention that at least one linking element has a length that exceeds the distance between its ends when the stent is in its expanded form.

The linking element permits improved radial and longitudinal flexibility of the mesh, whilst simultaneously retaining a good degree of structural integrity throughout the whole stent.

In one embodiment the mesh is formed from rows of diamond-like elements arranged longitudinally and linked together by connecting elements, at least one of which (preferably all of which) is a linking elements as defined above, for example comprises an "S"-shaped bend therein. Optionally, some of the points connecting two neighbouring diamonds in each element are absent to provide further flexibility within the mesh. An example is shown in Figure 38A.

In an alternative embodiment linking elements as defined above alternate with a straight section to form a zig-zag element. Preferably a number of such zig-zag elements are present in the stent and are arranged longitudinally. Each zig-zag element may be off-set relative to its neighbouring zig-zag elements and may

be joined thereto by a connecting element, which may itself be diagonally disposed and off-set from the apex of each zig-zag element. Examples are shown in Figures 36A and 37A.

The mesh stent described above may be produced by etching a metal sheet or tube. Desirably the stent is formed from shape memory material, for example nitinol.

Preferably the endovascular prosthesis described above comprises a stent of the form referred to here, for example having an "S"-shaped linking element. Most preferably the endovascular prosthesis comprises a stent having the mesh pattern shown in one of Figures 36 and 38.

Embodiments of the invention will now be described by way of example, with reference to the accompanying drawings wherein:

Fig. 1 is a plan view of basic elements of the metal mesh employed in the prosthesis of the invention;
Fig. 2 is a plan view of one side of one element of the mesh of Fig. 1 showing the dimensions in millimetres;
Figs. 3, 4 and 5 are plan views of alternative forms of the basic elements of the metal mesh;
Fig. 6 is a plan view of the development of a preferred form of membrane-expanding stent employed in the prosthesis of the invention;
Fig. 7 is a plan view of the development of a contralateral stent;
Figs. 8A-8D show various details of a stent having provision for adjustment of its length;
Figs. 9A, 9B and 9C are cross-sectional views

during and after the deployment of an anchor employed in the prosthesis of the invention;

Figs. 10-17 are semi-schematic sections through vascular anatomy, showing the successive stages in the emplacement of a prosthesis in accordance with the invention, by use of an introducer also in accordance with the invention;

Figs. 18A and 18B schematically depict one form of haemostatic valve in accordance with the invention;

Figs. 19A and 19B schematically depict another form of haemostatic valve in accordance with the invention;

Figs. 20 and 21 respectively depict a longitudinal elevation and an end view of a version of the valve of Fig. 19 modified for manual operation, with the valve being fully closed;

Figs. 22 and 23 respectively correspond to Figs. 20 and 21, but with the valve being partially opened; and

Figs. 24-35 show successive stages in the deployment of a prosthesis by means of an introducer in conjunction with a valve, all in accordance with the invention.

Figs. 36 shows a mesh pattern suitable for a stent of the present invention where the stent is shown an expanded form in A; the same stent is shown in an unexpanded form in B; and an enlarged view of the circled area of B is shown in C.

Fig. 37 shows an alternative mesh pattern suitable for a stent of the present invention wherein the stent is shown in A in an expanded form; the same stent is shown in unexpanded form in B; and an enlarged view of a portion of B is shown in C.

Fig. 38 shows an alternative mesh pattern suitable for a stent of present invention wherein the stent is

shown in A in an unexpanded form; the same stent is shown in unexpanded form in B.

For convenience, the mesh pattern of Figs. 36 to 38 is depicted in the form of a flat sheet. The mesh itself may either be produced from a sheet (which is welded) or a tube.

The endovascular prosthesis of the present invention incorporates a full-length stent which is fully articulated or partly articulated. The stent is of mesh form fabricated from a shape memory alloy, and makes use of the super-elastic properties of such alloys. The shape memory alloy may be a binary alloy such as a nickel/titanium alloy, or the alloy may be a tertiary alloy offering improved performance. The stent is covered with a sleeve of biocompatible fabric as a blood-tight membrane, the fabric preferably being as described in WO-A-98/05271.

The stent mesh is manufactured by cutting or etching memory alloy initially in the form of flat sheet or tube, allowing use of a range of mesh sizes and style of mesh patterns in stent production. Alternatively, the stent mesh may be of wire.

A basic stent mesh pattern is shown in Fig. 1, wherein the indicated linear dimensions are in millimetres. The diamond pattern of Fig. 1 is formed of a rhomboidal grid of elements (1) as shown in detail in Fig. 2 (wherein dimensions are in millimetres). The Fig. 2 stent mesh elements (1) are so shaped and dimensioned in order to minimise strain and stress levels as the mesh expands from its fully closed form to its fully open form, with a concomitant increase in the length of the short diagonal of the mesh unit (the horizontal

node separation as shown in Fig. 1) from 3mm to 8.43mm.

It is to be particularly noted that each mesh joint as shown in Fig. 1 is a tri-nodal joint, such that by extending the horizontal and/or vertical legs between the diagonal elements, the mesh dimensions can be selectively altered without affecting the basic geometry. Fig. 3 (which is essentially the same as Fig. 1) shows the basic definitions of the "x" dimension (horizontal) and the "y" dimension (vertical), while Fig. 4 shows an extension of the "x" dimension of the horizontal node link, and Fig. 5 shows an extension of the "y" dimension of the vertical node link. Mesh patterns as depicted in Figs. 4 and 5 are also suitable for use in the present invention.

Such design flexibility in respect of mesh dimensions allows the creation of a stent mesh pattern which incorporates segments of various lengths, diameters, articulation, or function as may be required.

Once a particular mesh pattern is selected, for fabrication from a flat sheet the initially flat mesh may be rolled up into a generally tubular shape which can then be secured by mutually welding the now-adjacent points which were initially on opposite edges. Alternatively, the mesh pattern can be produced by etching a tube of shape memory material or by arranging and welding wire into the form required.

The mesh pattern for a bifurcated aneurysm repair stent 100 is shown in Fig. 6 in flat form (ie before being rolled up into a generally tubular shape or as would be achieved by selection cutting and a tubular member formed from a single piece of material). Where the stent is formed from wire, it is possible for a flat

sheet of the type shown in Fig. 6 to be formed and then welded, but more generally the stent will be produced in tubular form and in such an embodiment the Fig. 6 shows the mesh pattern in the continuous circumference of the stent (at least for segments A, C and F). The bifurcated stent 100 is in a number of functionally different segments which are individually denoted in Fig. 6 by respective letters A to F. The functions of these segments are as follows:-

SEGMENT

A **Supra Renal Aortic Anchor**
This is a single diamond mesh designed to anchor into the aorta above the renal arteries and will remain uncovered of fabric to allow for incorporation into the vessel wall. Its fully expanded diameter will be the same or greater than the internal diameter of the vessel.

B **Hanger Links from Supra Renal (A) to Infra Renal Segments**
These links (2), which are designed to sit dorsoventrally, will allow the stented graft (100) to be positioned just below the renal arteries while the system remains anchored by the supra renal segment (A).

C **Aortic Sealing Segment**
This segment makes use of the basic mesh pattern (see Fig. 1) to create a full diameter stented graft that will sit just below the renal arteries and seal well against the vessel wall.

D **Bifurcation Segment**
At this segment the full diameter Aortic Stent

tapers down to form the bifurcation for the graft with one leg truncated (3) and the other leg (5) continuing (E). The truncated leg (3) may have a reverse taper at the tips to aid location and sealing of the independent contralateral leg (110).

E **Articulated Leg** (5)
This segment consists of a mesh pattern where a series of the leg sections have been omitted (4) in order to give the stented graft some degree of flexibility and allow it to accommodate a tortuous vessel while maintaining both some axial rigidity and radial strength. This mesh may form a complete circumference of the graft leg of a diameter that is independent of the diameter of the Aortic Stent segment diameter or it may only form a partial circumference thus increasing flexibility.

F **Full Iliac Stent**
This segment makes use of a basic mesh pattern to create a full circumference stent of a diameter independent of the diameter of the Aortic Stent segment.

Alternative mesh patterns (see Figs. 36 to 38) may be used in a bifurcated stent of the form shown in Fig. 6.

The bifurcated stent 100 has one integral full-length leg, the articulated leg 5 (see Figs. 13-17) and merely a socket 6 formed from the short leg 3 for the contralateral leg 110. A suitable mesh pattern for the contralateral leg 110 is shown in Fig. 7, where a basic mesh has a series of connecting sections omitted in order to give some degree of flexibility and yet still

retain some axial rigidity and radial strength. Details of the variants of the basic pattern are shown in the fragmentary views of Figs. 7A, 7B and 7C, while details of the weld tab (for securing the mesh in its eventual tubular form) are shown in the fragmentary view of Fig. 7D.

Fig. 7A shows the base of a diamond shaped section where a connecting section has been omitted.

Fig. 7B shows basic sections of two adjacent diamond shaped sections which are not joined together.

Fig. 7C shows an apex of a diamond shaped section, wherein the apex diamond shaped section is not attached to another diamond shaped section.

Figs. 8A-8D show a bifurcated stent 120 which is a modification of the stent 100 of Fig. 6. The modification of the stent 120 consists of a secondary stent 122 located in the main leg 5 of the stent 120. By attaching the trailing edge 8 of the fabric sleeve 9 to the secondary stent 122, the secondary stent 122 and fabric sleeve 9 can be selectively pulled down (eg from the Fig. 8A configuration to the Fig. 8B configuration) to increase the effective length of the stent 120 from L1 to L2 prior to deployment of the secondary stent 122 (Figs. 8C and 8D).

Upon elongation of the secondary stent 122 any unrequired portion 9A (see Fig. 8C) of sleeve 9 will protrude into the central lumen of the prosthesis and may interfere with the blood flow through the vessel possibly even inducing blood clotting on the surface of the material. This may be prevented by use of a suitably positioned third stent 123 thus preventing the portion of spare material 9A from interfering with the

blood flow (see Fig. 8D). The third stent 123 effectively clamps the spare material 9A against the leg 5 of the primary stent 100 and against the secondary stent 122.

Fig. 9A shows, in semi-schematic form, a longitudinal section of a hollow capsule 130 for retaining and eventually selectively deploying the anchor segment 'A' of the stent 100 (Fig. 6). The distal end 132 of the capsule 130 is mounted on a flexible control member 320, and the other end 136 of the capsule 130 is detached and temporarily held within the capsule body 138. The detached end 136 is urged outwardly by a compression spring 140 self-retained on the control member 320 between the ends 132 and 136; however, the detached end 136 is temporarily held back by the presence inside the capsule body 138 of the radially compressed anchor stent 100A. The partial deployment of the anchor 100A is shown in Fig. 9B, and will be more fully detailed with reference to Fig. 14. At the completion of anchor deployment (Figs. 9C and 15), the detached end 136 is spring biased back to its end-capping position on the body 138 where it facilitates withdrawal of the capsule 130 (downwards as shown in Figs. 9C and 16) while avoiding the trauma that would otherwise be induced by the open end of the capsule body 138. The fully deployed anchor stent 100A is not shown in Fig. 9C.

Figs. 10-17 show (in semi-schematic and fragmentary form) the sequence of steps involved in the emplacement of the Fig. 6 stent 100 (in tubular form and radially collapsed inside a sleeve of biocompatible fabric) into an aortic system 200 such that the stent 100 and its fabric sleeve 9 will eventually shunt an infra-renal aneurysm 210 but without blocking or inducing

unacceptable turbulence in the side-branching renal arteries 220, even though taking advantage of the superior supra-renal anchoring site 230. The stent 100 and its sleeve 9 are initially radially collapsed and the stent 100 is located inside a guide tube 300 immediately behind the capsule 130 holding the similarly collapsed anchor stent. The guide tube 300 is capped by a dilator 310, and the assembly is fed along a guide wire 134 previously inserted into the aortic system 200 (Fig. 10). The dilator 310 (Fig. 10) is removed (Fig. 11), and the capsule 130 extended from the distal end of the guide tube 300, but the anchor stent 100A (Fig. 15) is not yet extended. Utilising X-rays or other monitoring means, the fabric-covered portion of the stent 100 is suitably located to span across the aneurysm 210 (Fig. 12) and its deployment is started by controlled withdrawal of the guide tube 300, such withdrawal continuing until the stent 100 (other than its anchor segment 100A) is fully emplaced so as to span the aneurysm (Fig. 13).

Final adjustments in the position of the main stent 100 are made while such adjustments are relatively easy prior to anchor deployment, and then the control member 320 is gently advanced into the patient's body so as to push the capsule 130 upwards (Fig. 14). As the capsule 130 advances, the anchor segment 100A is held back by the hanger links 2 (or 100B) (Fig. 6) attached to the lightly self-anchored main part 100C of the stent 100, resulting in the anchor stent 100A being pulled out of the capsule 130 (Figs. 9B and 14), and eventually in complete freeing of the anchor stent 100A (Fig. 15) which anchors in the supra-renal aortic wall 230. The capsule 130 closes itself (Figs. 9C and 16) and is withdrawn (Fig. 17) by removal of the guide wire 134.

The anchor stent 100A firmly anchors in the supra-renal wall, and thereby firmly anchors the remainder of the prosthesis 100 in an aneurysm-spanning position through the intermediary of the hanger links 2 (or 100B). By suitably positioning the links 2 (or 100B) with respect to the remainder of the stent 100, it is readily arranged such that neither of the links 2 (or 100B) crosses the renal arteries 220, so that despite taking advantage of supra-renal anchoring, the prosthesis 100 causes negligible disturbance to renal blood flow. By having the anchor stent 100A uncovered by fabric 9, the bare metal mesh of which the anchor stent 100A is formed readily imbeds in the vascular wall and becomes incorporated into its structure.

The guide tube 300 of the introducer enters the patient's body through an incision extending into a suitable blood vessel. Excessive loss of blood through the lumens of the prosthesis will result unless precautions are taken to seal the area, but it must still be necessary to extend and retract the necessary parts of the introducer with reasonable facility. Accordingly, a haemostatic valve is a desirable adjunct to the present invention of the prosthesis and its introducer.

One suitable form of haemostatic valve 400 is shown in longitudinal cross-section in Fig. 18A. The valve 400 comprises an annular housing 410 having within it a silicone rubber sleeve 420 retained within the opposite ends of the housing 410 by means of outwardly-acting clamp rings 430. The space between the inside of the housing 410 and the outside of the sleeve 420 (between its opposite ends) is selectively pressurisable via an inflation port 440 formed in the housing 410.

As shown in Fig. 18A, there is no pressurisation, the sleeve 420 is released and the valve 400 is fully opened. As shown in Fig. 18B, pressurisation is applied via the inflation port 440, which collapses the sleeve 420 to pinch it shut, either onto itself as shown or onto a guide tube or the like (not shown in Figs. 18A or 18B) passing through the valve 400. By sealing one end of the valve 400 to the outer surface of the inducer (either directly or through the intermediary of an adaptor (not shown)), the valve 400 can be kept pressurised to prevent blood loss, and depressurised only when (and only to the extent required) to pass a tube or instrument through the sleeve 420.

Another suitable form of haemostatic valve 500 is shown in longitudinal cross-section in Fig. 19A. As with the valve 400, the valve 500 has an annular housing 510. A control ring 520 is rotatably mounted on the right-hand end of the housing 510. A silicone rubber sleeve 530 is located inside the housing 510, with its left end secured to the housing 510 by a clamping ring 540, and its right end secured to the control ring 520 by a further clamping ring 550.

As shown in Fig. 19A, the control ring 520 is in a rotational position in which the sleeve 530 is untwisted and fully open. By turning the control ring 520 relative to the housing 510, the sleeve 530 is twisted and eventually (with sufficient control ring rotation) collapses on itself as shown in Fig. 19B, thereby to pinch off blood flow through the valve 500.

Figs. 20-23 show a haemostatic valve 600 which is a modified form of the valve 500 (Figs. 19A and 19B) adapted for manual operation and to be spring-biased

closed. The components of the valve 600 are as follows:-

601 Adaptor for an Introducer tube. (Different sizes of tube can be fitted to different adaptors);

602 O-Ring-seals between rear face of adaptor and front face of rotating finger grip;

603 Outer body of valve - incorporates fixed finger grip;

604 Rotating finger grip - pushing this against fixed grip helps to untwist the silicone tubing 606 against the spring torque and open central hole 610. This makes insertion of dilators and graft cartridges much easier;

605 Spring - Torsion spring keeps silicone tubing twisted shut like an iris, and keeps rotating finger grip 604 fully open;

606 Silicone rubber tube - twisted through 250 degrees maximum. Closing finger grips 604 together reduces twist to 160 degrees, partially opening the central hole 610;

607 Fixed sleeve anchor for silicone tube 606 - this provides a location for the torsion spring 605 and an anchor and seal for the tube 606;

608 Inner sleeves (at each end of silicone tube 606) - these trap and bond the silicone tube 606 into their anchor sleeves; and

609 Bayonet socket for fitting Dilators and graft cartridges.

610 Central aperture of the haemostatic valve 600 which can be opened and closed to allow items to be admitted or withdrawn from the patient with the minimum blood loss.

Figs. 20 and 21 show the valve 600 closed under the biassing influence of the spring 605 which twists the

silicone rubber tube or sleeve 606 shut (as in the valve 500 of Figs. 19A and 19B). By manually pinching the finger grips 603 and 604 together, as shown in Figs. 22 and 23, the sleeve 606 is untwisted sufficiently to admit the dilator 310 of the introducer without undue resistance, but without undue clearance that would allow excessive leakage of blood from the patient. The central opening 610 can be opened and closed as required to facilitate the insertion and/or removal from the patient of the introducer (and other items) with the minimum of blood loss.

Figs. 24-35 show a sequence of steps involved in utilising the introducer and haemostatic valve of the invention to emplace the endovascular prosthesis of the invention in the aorta to span across a sub-renal aneurysm, with the prosthesis having the advantage of supra-renal anchorage but without interfering with renal blood flow.

While certain modifications and variations have been described above, the invention is not restricted thereto, and other modifications and variations can be adopted without departing from the scope of the invention.

Figure 24 shows a basic introducer assembly 11 which may be used to introduce a stent 12 (see Fig. 25A). The assembly 11 includes the capsule 130 for deploying the anchor stent 100A. Stent 12 and sleeve 13 (see Fig. 25B) may be assembled and structured together to form an endovascular prosthesis 14 according to the invention (see Fig. 25C). In use, the stent 12 and sleeve 13 are compacted in a collapsed form and fitted within a cartridge 15 (shown in outline for clarity in Fig. 26) which are fitted to an introducer assembly 11.

The capsule 130 is shown containing the anchor stent 100A. A complete introducer assembly 16 is shown in Fig 27 and includes a bayonet attachment 23A.

Figure 28 illustrates the introducer sleeve 17 and a dilator tip 22. A guide wire 134 is fed through the dilator tip 22 as sleeve 17 is inserted into the patient. A haemostatic valve 19 of the type previously described herein is attached to the dilator 23 of which only handle 20 is visible in the diagram. The haemostatic valve 19 may be opened and closed by use of a rotatable handle 21.

Figure 29 illustrates the dilator 23 once it has been withdrawn from the introducer sleeve 17. In order to facilitate withdrawal of the dilator 23 from the introducer sleeve 17 the haemostatic valve 19 is opened by rotating the rotatable handle 21 in the direction of the arrow. The dilator 23 is unlocked via the bayonet attachment shown as 23A. The dilator 23 is completely withdrawn from the sleeve 17 and the guideline 134, leaving the guide wire 134 and the sleeve 17 within the body of the patient.

The complete introducer assembly 16 can then be passed along the introducer sleeve 17 by attaching the guide wire 134 to the nosecone 130 of the introducer assembly 16 and utilising the bayonet attachment 23A to lock the introducer assembly 16 and haemostatic valve 19 together (see Fig. 30). The haemostatic valve 19 will be opened just sufficiently to allow the passage of the nose cone 130 and the rest of the endovascular prosthesis into the patient's body whereupon the haemostatic valve is closed (see Fig. 31). The prosthesis is then deployed by pushing the introducer assembly in at point A, as indicated, (see Fig. 32).

Once the nosecone 130 appears at point C (this being monitored continuously) handle 15 is used to pull the whole apparatus backwards (along arrow B) such that the introducer sleeve 17 is pulled down the prosthesis (as opposed to the prothesis being pushed out of the sleeve 17). Fig. 32 shows the partial deployment of the prosthesis and in Fig. 33 the prosthesis is almost fully deployed. The complete deployment of the prosthesis is achieved when the sleeved section of the stent is clear of the introducer sleeve 17. After checking correct positioning of the main stent, the nosecone 130 is pushed forward to release the supra-renal anchor 100A as previously described (see Fig. 34).

The rear of the nosecone 130 is tapered (see Figs. 34 and 9C) for easy withdrawal. Removal of the introducer assembly 16 can be achieved by withdrawing the nosecone 130 through the fully deployed prothesis and withdrawing the introducer sleeve 17 from haemostatic valve 19. The guide wire 134 and introducer sleeve 17 are all removed as one assembly (see Fig. 35).

Various mesh patterns suitable for a stent according to the invention are shown in Figs. 36-38. The mesh illustrated in Fig. 36A comprises a diagonally offset row 30 of diamond-like shapes 31, the diamonds being connected together to form a horizontal row by a linking elements 32 having two bends therein. Thus the full length of linking elements 32 exceeds the direct length between the points connected thereby. These linking elements 32 give flexibility to the longitudinal and circumferential expansion of the stent. Rows 30 of the diamond-like shapes 31 are connected in a longitudinal direction by diagonally disposed struts 33. Fig. 36B is the unexpanded form of

the mesh of Fig. 36A and Fig. 36C is an enlarged view of the circled portion of Fig 36B illustrating the detail of the connections.

An alternative mesh suitable for a stent of the present invention is shown in Figs. 37A, B and C. The mesh illustrated in Fig. 37A may be viewed as a series of zig-zag elements 40 arranged in a longitudinal manner and connected above and below to its neighbouring zig-zag element 40 by diagonally disposed struts 41. Each zig-zag element 40 is characterised by alternate struts 42 of the zig-zag having an additional "S"-shaped bend 43 therein. Struts 42 therefore have a greater length that the direct distance between their ends. Alternating with struts 42 to form the zig-zag element 40 are straight struts 44. The mesh illustrated in Fig. 37B is a plan view of an unexpanded mesh. Fig. 37C is an enlarged view of a section of Fig. 37B wherein typically the wire thickness is 0.149 mm.

Fig. 38A illustrates an alternative mesh suitable for a stent of the present invention mesh. In this embodiment, a row 50 of connected diamond-like sections 51 are arranged longitudinally and connected to adjacent rows of diamond-like sections via linking elements 52 on alternate diamonds. The linking elements 52 are approximately "S"-shaped. In the embodiment illustrated linking elements 52 are aligned longitudinally, but it may be advantageous for these to be off set in neighbouring rows. In the mesh illustrated the connecting points 53 in alternate neighbouring diamonds have been omitted. This imparts greater flexibility to the mesh. Fig. 38B is a view of the unexpanded mesh of Fig. 38A wherein the approximately "S"-shaped linking elements 52 are clearly visible between each of the rows 50 of diamond-

like sections 51.

In each of Figures 36-38 the "S"-shaped linking element or "S"-shape vertices of the individual sections impart increased flexibility to the stents, whilst maintaining the structural integrity thereof.

CLAIMS

1. An endovascular prosthesis for a vascular aneurysm, the prosthesis comprising a tubular membrane means which is substantially impermeable to blood and which is disposable to convey blood between substantially non-aneurysmal regions on either side of the aneurysm, the prosthesis further comprising selectively deployable anchor means for anchoring in the vascular wall at an anchoring location displaced from the aneurysm, the anchor means being linked to the tubular membrane means by link means comprised in the prosthesis, the link means being such as to cause minimal turbulence in side-branching blood vessels branching from a point between the aneurysm and the anchoring location

2. An endovascular prosthesis as claimed in Claim 1 where in said anchor means comprises an expandable metal mesh annular stent.

3. An endovascular prosthesis as claimed in Claim 2 wherein said anchor means is unclad by any membrane or fabric.

4. An endovascular prosthesis as claimed in any one of Claims 1 to 3 wherein the link means comprises at least one longitudinally extending strut or wire.

5. An endovascular prosthesis as claimed in any one of Claims 1 to 4 wherein the tubular membrane means comprises a sleeve of fabric located over an expandable metal mesh tubular stent which is in a radially collapsed form for emplacement of the

prosthesis and which is expandable when located to shunt the aneurysm.

6. An endovascular prosthesis as claimed in any one of Claims 1 to 5 wherein the anchor means stent and the tubular membrane means stent are each formed from shape memory material.

7. An endovascular prothesis as claimed in Claim 6 wherein the anchor means stent and the tubular membrane means stent are each formed from nitinol.

8. A stent formed from a mesh characterised in that said mesh comprises a linking element wherein each end of said element is connected at a connecting point to the mesh and wherein the length of said element exceeds the distance between the connecting points.

9. A stent as claimed in Claim 8 wherein said linking element comprises an "S"-shaped bend.

10. A stent as claimed in Claim 9 wherein said linking element is substantially "S"-shaped.

11. A mesh stent wherein the mesh is formed from rows of diamond-like elements arranged longitudinally and linked together by connecting elements, at least one of which is a linking element as defined in any one of Claims 8 to 10.

12. A mesh stent having a zig-zag element formed from linking elements as defined in any one of Claims 8 to 10 alternating with straight sections.

13. A stent as claimed in any one of Claims 8 to 12

formed from shape memory material.

14. An endovascular prosthesis as claimed in any one of Claims 1 to 7 comprising a stent as claimed in any one of Claims 8 to 13.

15. An introducer for endovascular emplacement of an endovascular prosthesis according to any one of Claims 1 to 7 or 14, the introducer comprising a flexible tubular guide means externally dimensioned for passage along a vascular duct from an extracorporeal location to the site of the aneurysm and to the anchoring location, the guide means being internally dimensioned to encompass the prosthesis in its initially radially collapsed state without preventing controlled longitudinal displacement of the prosthesis relative to the guide means during emplacement of the prosthesis, the introducer further comprising a hollow capsule for containing the anchor means in an initially radially collapsed state, one end of the capsule being detached from the remainder of the capsule and inserted inside the remainder of the capsule to lie within or adjacent the other end of the capsule such as to leave the remainder of the capsule between said inserted one end and the other end of the capsule for containing the collapsed anchor means, the introducer additionally comprising displacement control means for longitudinally displacing the capsule with respect to the tubular guide means, the introducer further comprising capsule end replacement means for replacing said one end of the capsule following deployment of the anchor means whereby to facilitate withdrawal of the capsule following emplacement of the prosthesis.

16. An introducer as claimed in Claim 15 wherein the capsule end replacement means comprises spring means disposed within the capsule between the opposite ends thereof to urge the detached end of the capsule towards its replaced position.

17. An introducer as claimed in Claim 15 wherein the capsule end replacement means comprises a Bowden cable means having a core wire threaded through the longitudinal axis of the introducer as a guide wire for the introducer, and having a Bowden sheath coupled to the detached end of the capsule.

18. A surgical package comprising the operative combination of an endovascular prosthesis as claimed in any one of Claims 1 to 7 or 14 and an introducer as claimed in nay one of Claims 8 to 10, the tubular membrane means of the prosthesis being in an initially radially collapsed configuration and located within the tubular guide means, the anchor means of the prosthesis being in an initially radially collapsed configuration and located with the capsule, the anchor means being linked to the tubular membrane means by the link means such that the anchor-encompassing capsule is also linked to the tubular membrane means, the capsule being disposed at the leading end of the tubular guide means, the displacement control means being threaded through the tubular guide means and through the tubular membrane means.

19. A surgical package as claimed in Claim 18 wherein the displacement control means extends through the end of the tubular guide means remote from the end of the guide means initially holding the prosthesis for extracorporeal control of the

displacement of the capsule.

20. A haemostatic valve comprising an elastomeric sleeve, a first end of the sleeve being sealed to a first sealing means, a second end of the sleeve being sealed to a second sealing means, and pinch control means for controllably pinching the sleeve where it extends between the two sealing means whereby controllably to seal around the tubular guide means or the displacement control means as it passes through the sleeve.

21. A haemostatic valve as claimed in Claim 20 comprising coupling means to allow connection and disconnection to the introducer.

22. A haemostatic valve as claimed in either one of Claims 20 and 21 wherein the pinch control means comprises rotation control means for controllably inducing relative rotation of the first and second sealing means about a common axis.

23. A haemostatic valve as claimed in Claim 22 wherein the rotation control means comprises bearing means rotationally coupling the two sealing means for relative rotation about a common axis, spring means acting between the two sealing means to bias them into relative rotation in a sense tending to induce rotational collapse of the sleeve, and manually engageable means attached to or forming part of the sealing means by which the bias of the spring means may be controllably counteracted by the application of manual force such as controllably to open the valve by a selected amount.

24. Use of a haemostatic valve as claimed in any one of Claims 20 to 23 in combination with the surgical package of Claim 19.

25. A surgical package as claimed in Claim 19 further comprising a haemostatic valve means as claimed in any one of Claims 20 to 23.

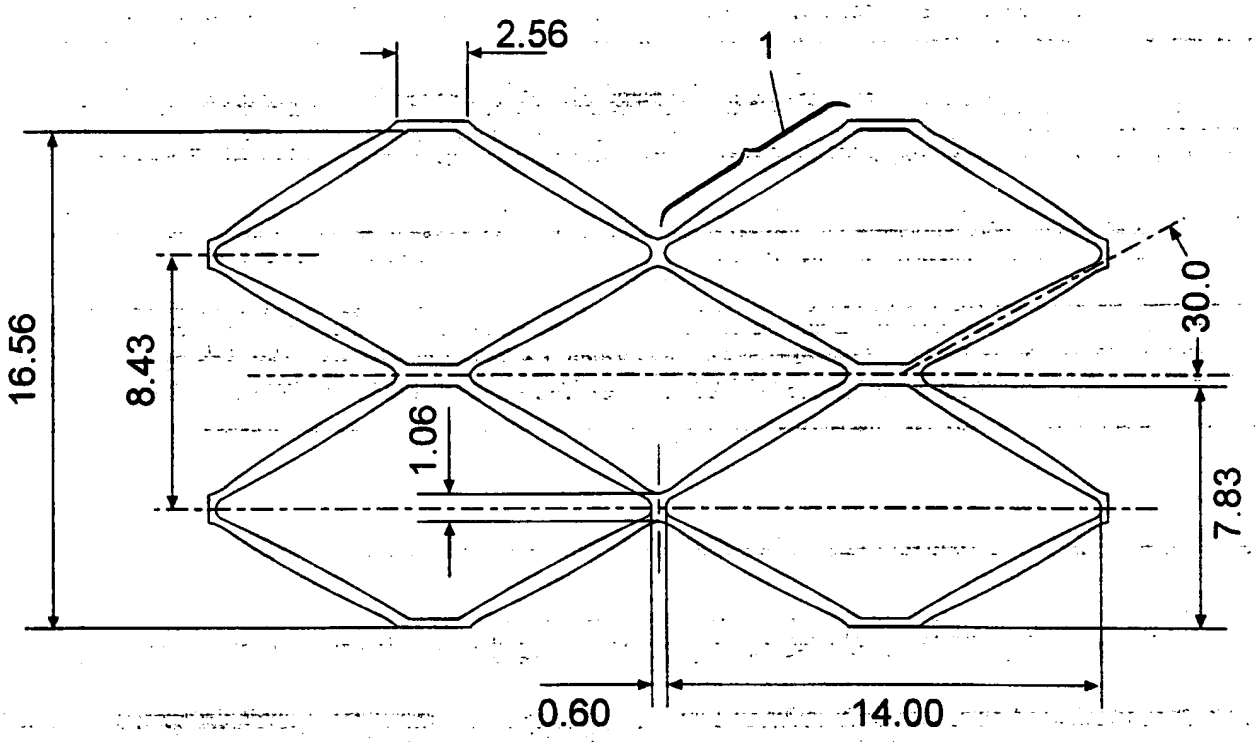


Fig. 1

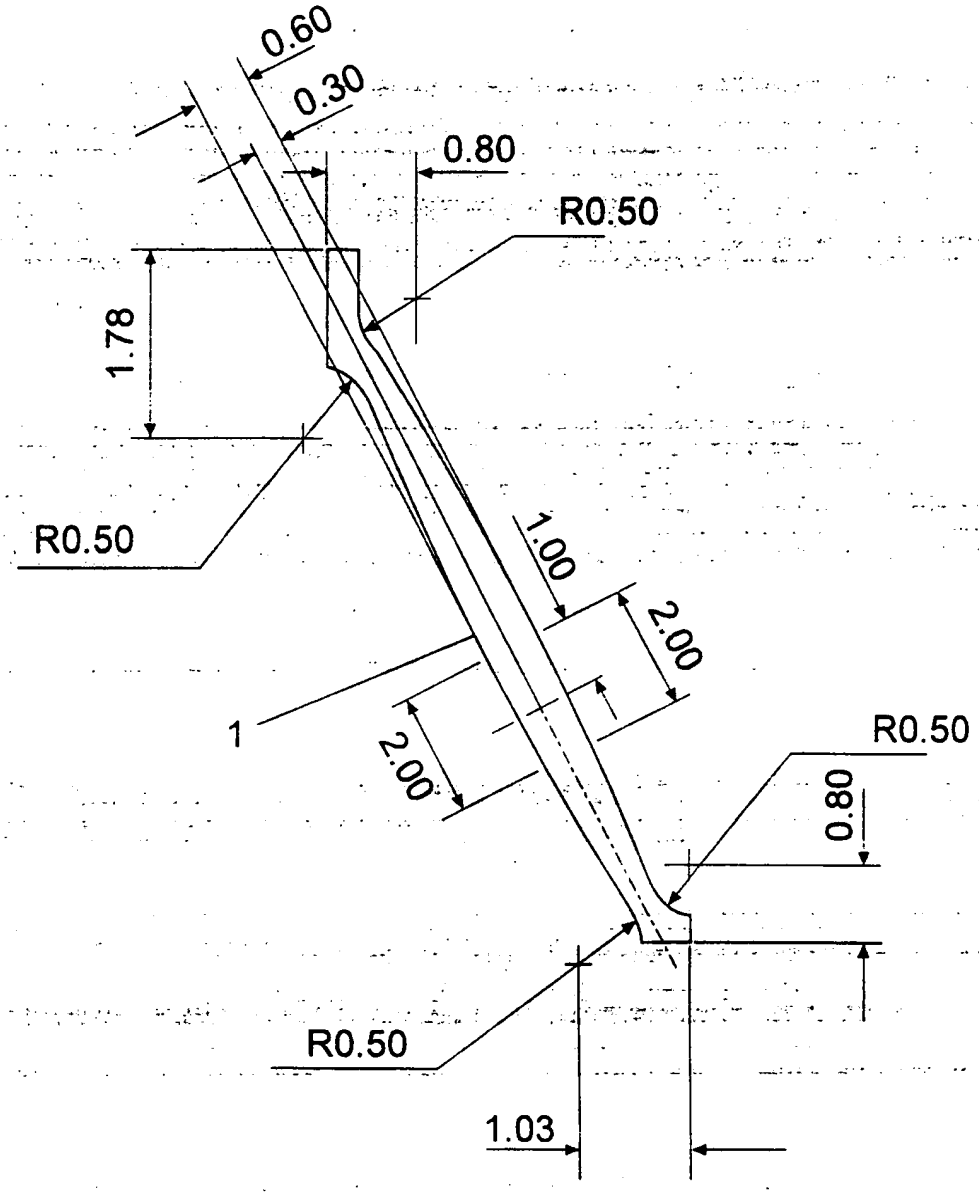


Fig. 2

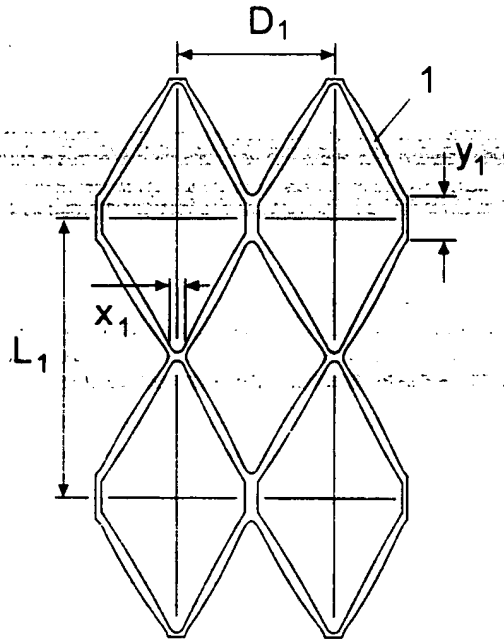


Fig. 3

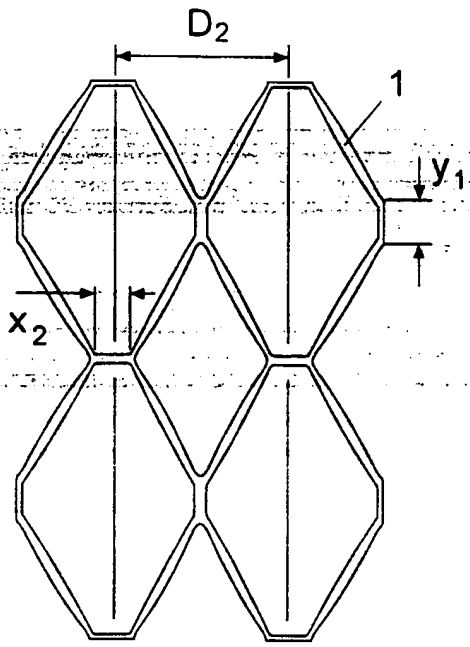


Fig. 4

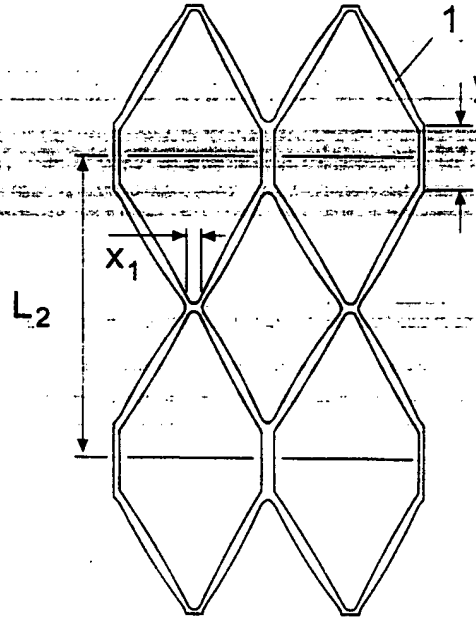


Fig. 5

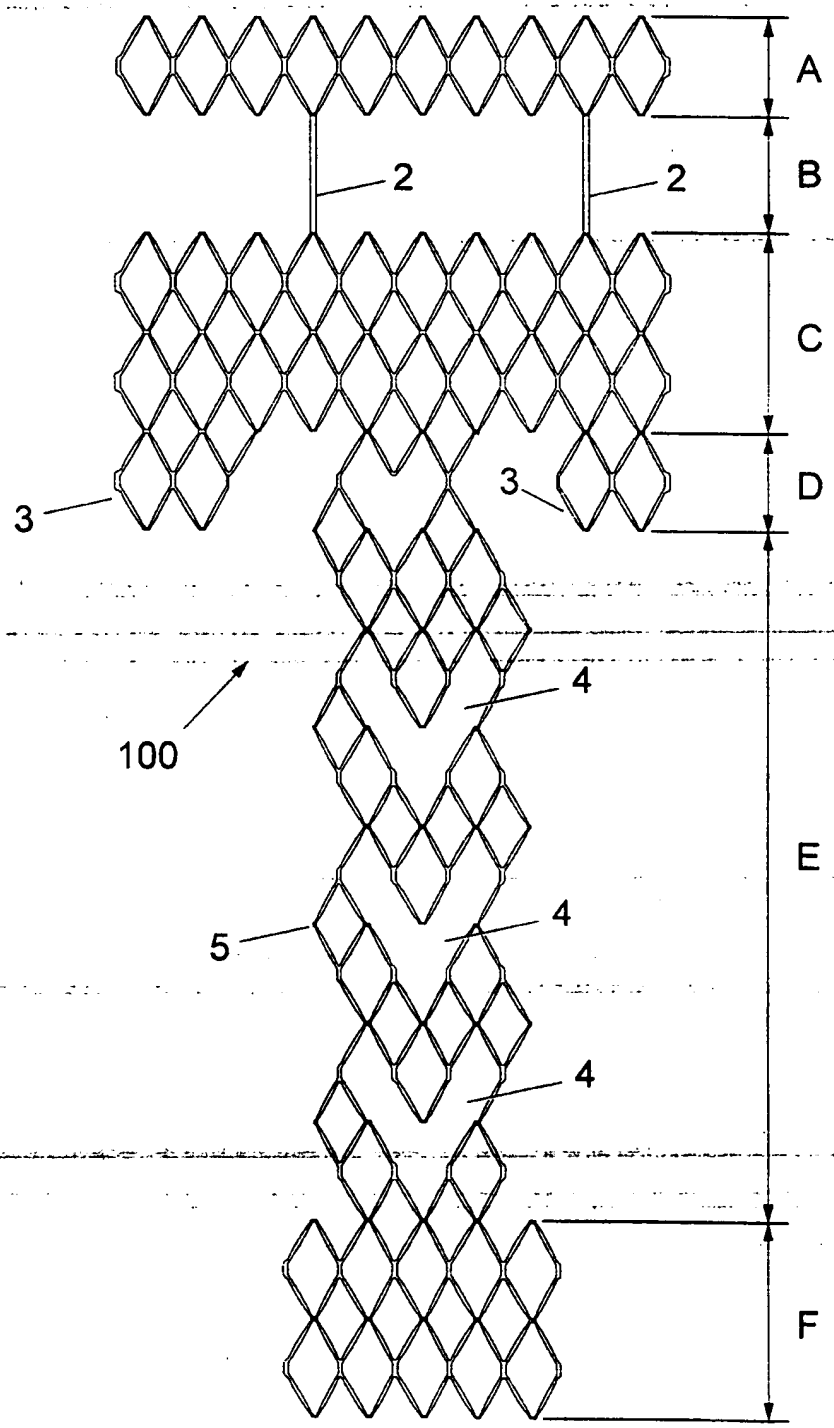


Fig. 6

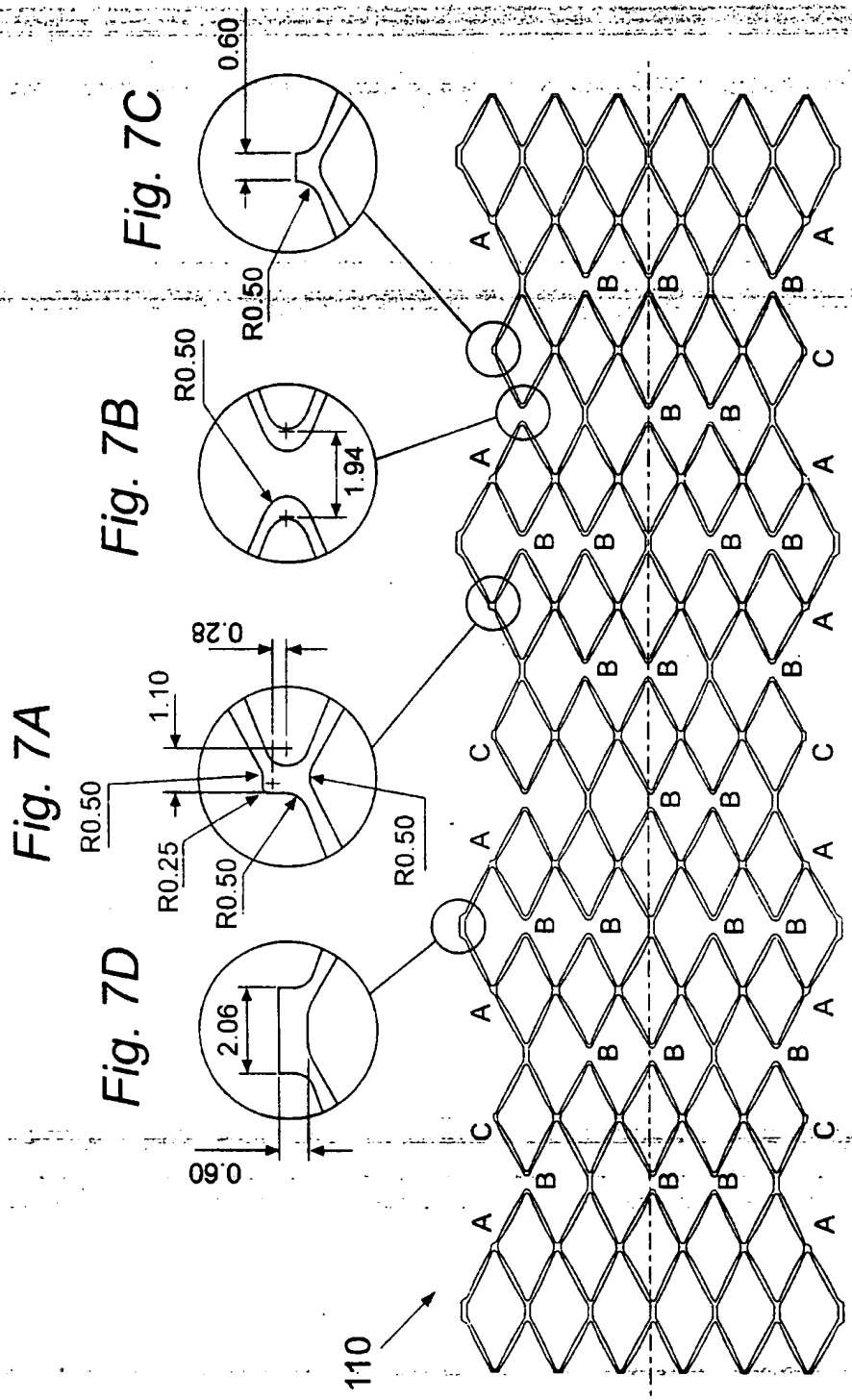


Fig. 7C

Fig. 7B

Fig. 7A

Fig. 7D

Fig. 7

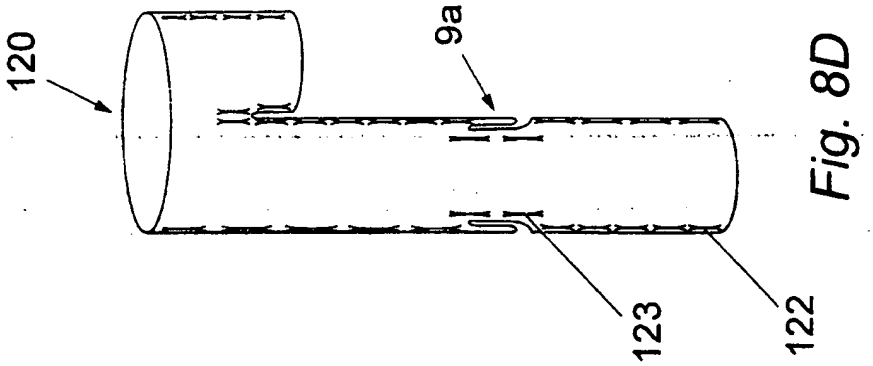


Fig. 8D

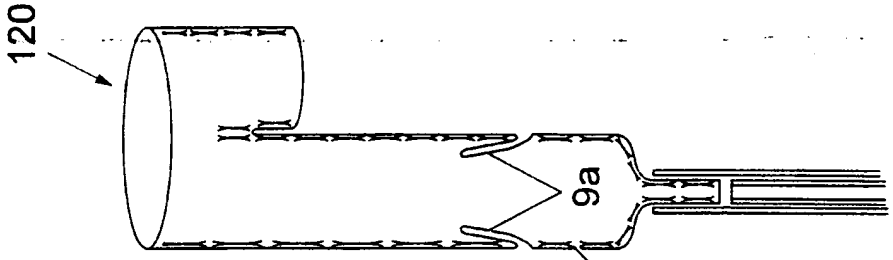


Fig. 8C

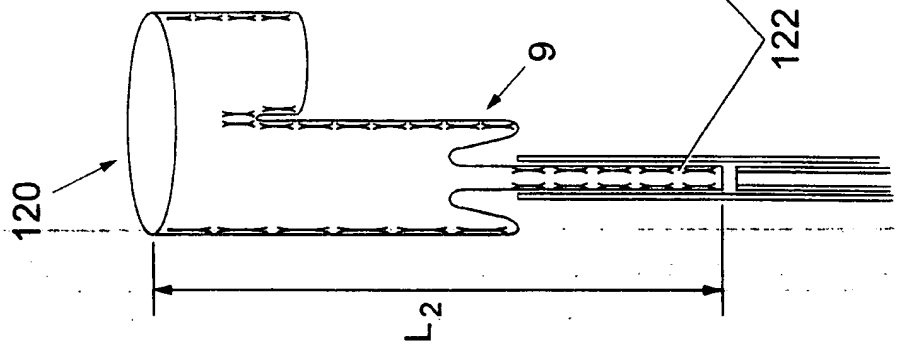


Fig. 8B

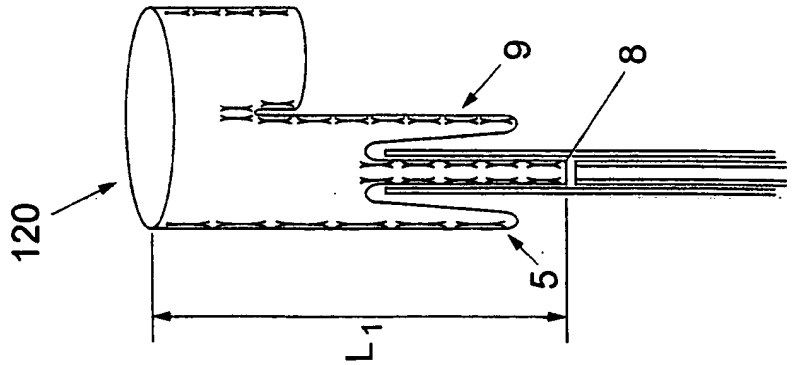


Fig. 8A

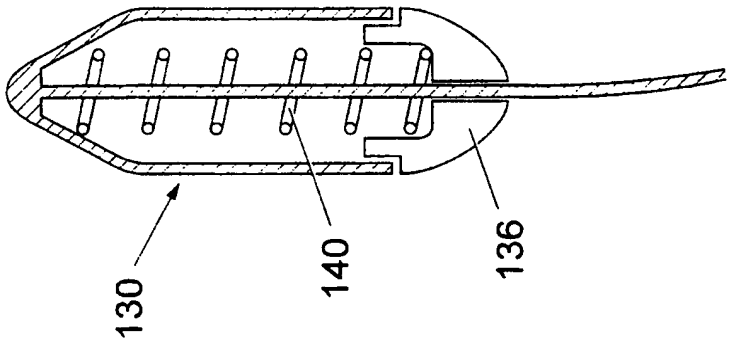


Fig. 9C

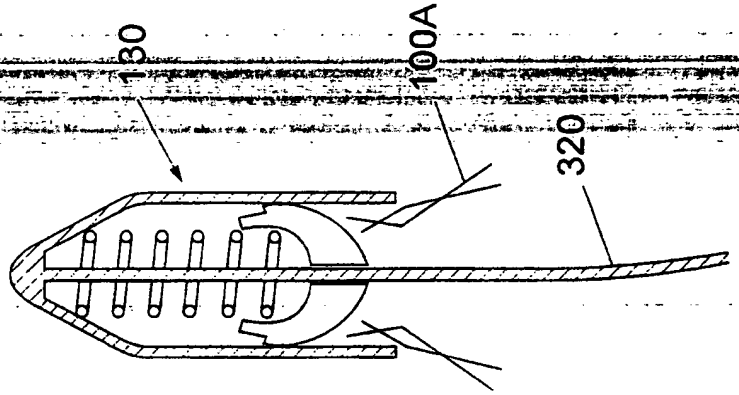


Fig. 9B

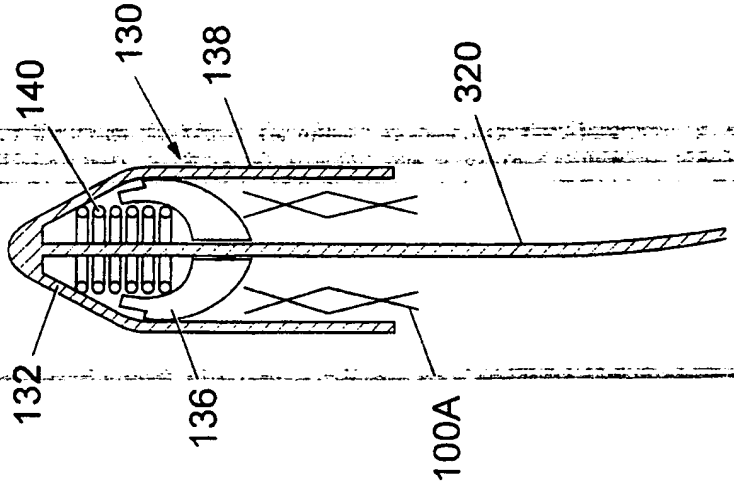


Fig. 9A

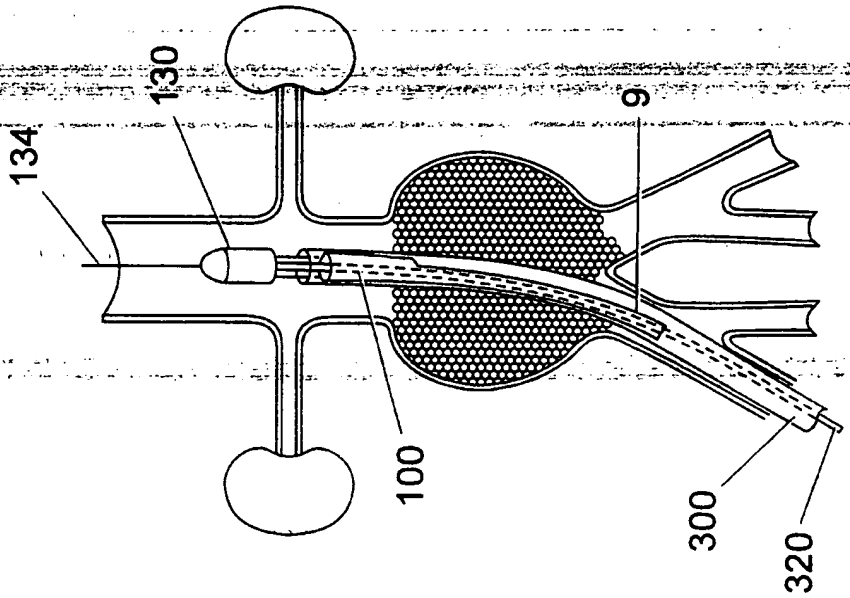


Fig. 11

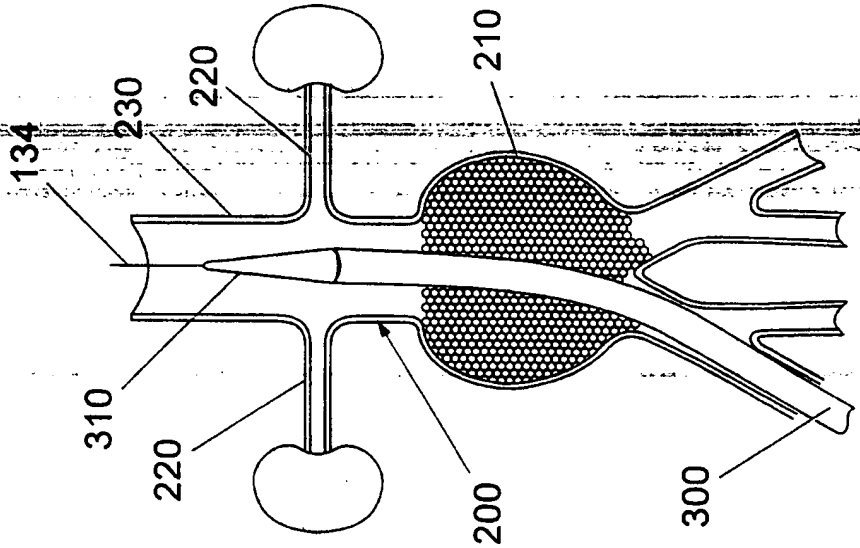


Fig. 10

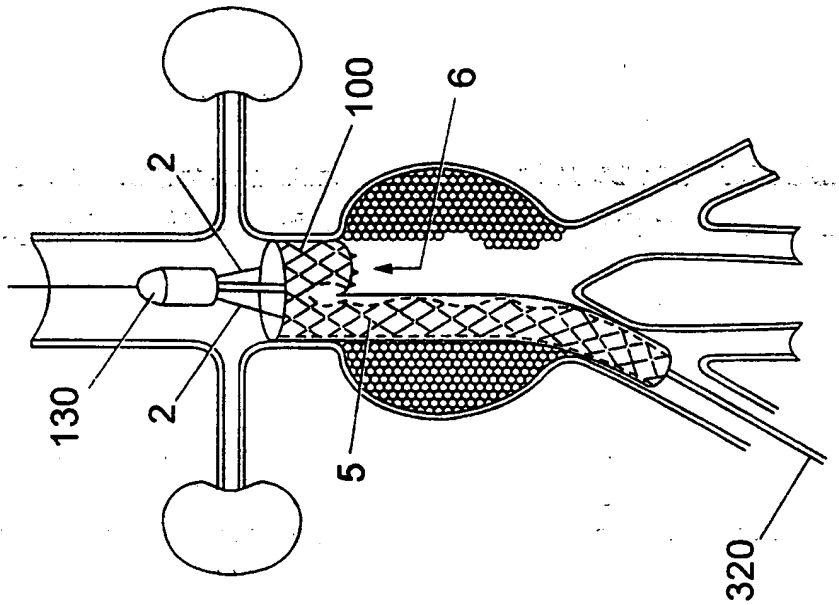


Fig. 13

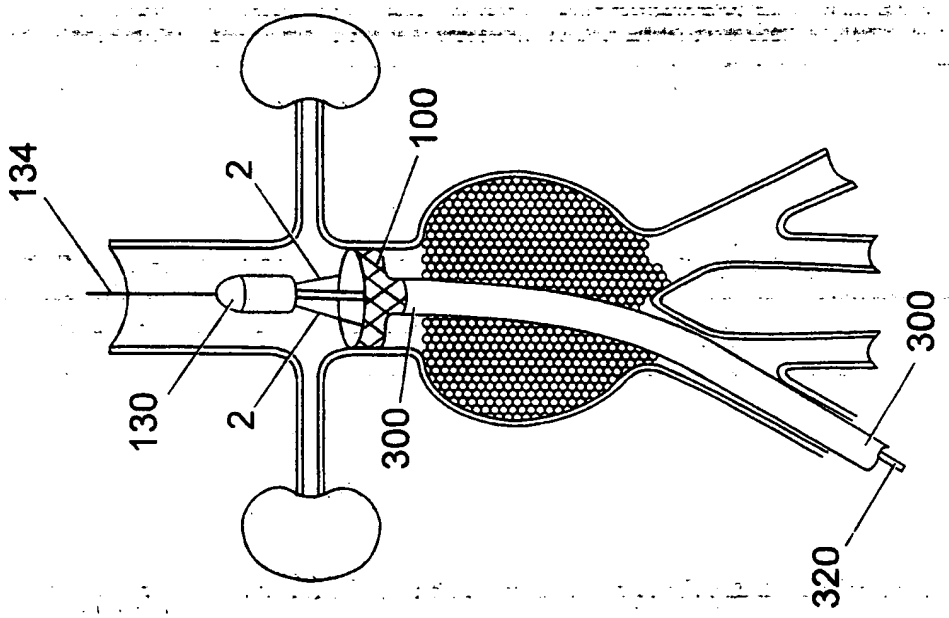


Fig. 12

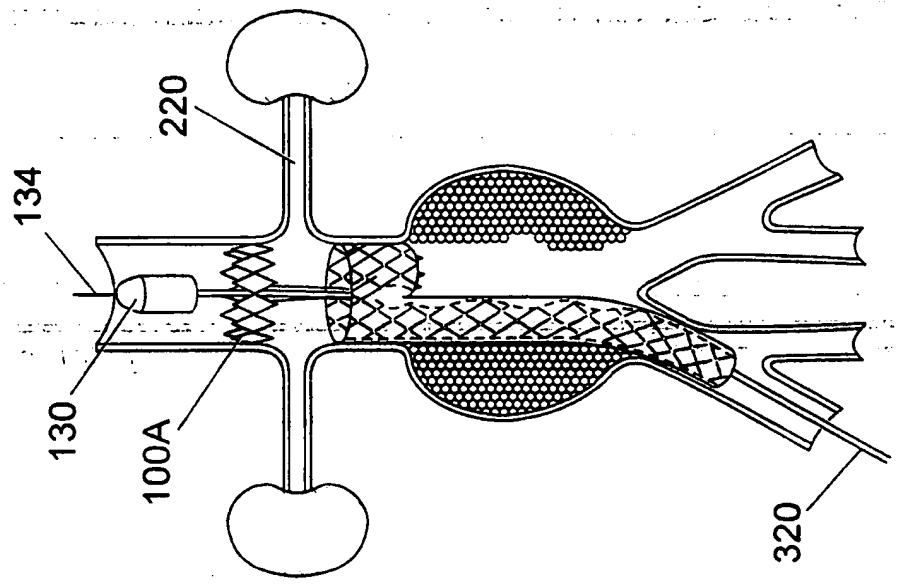


Fig. 15

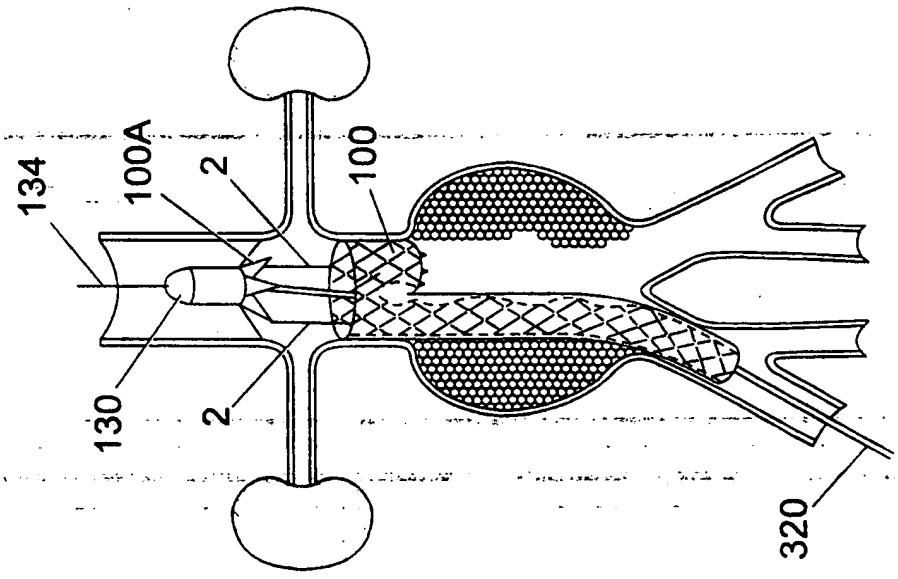


Fig. 14

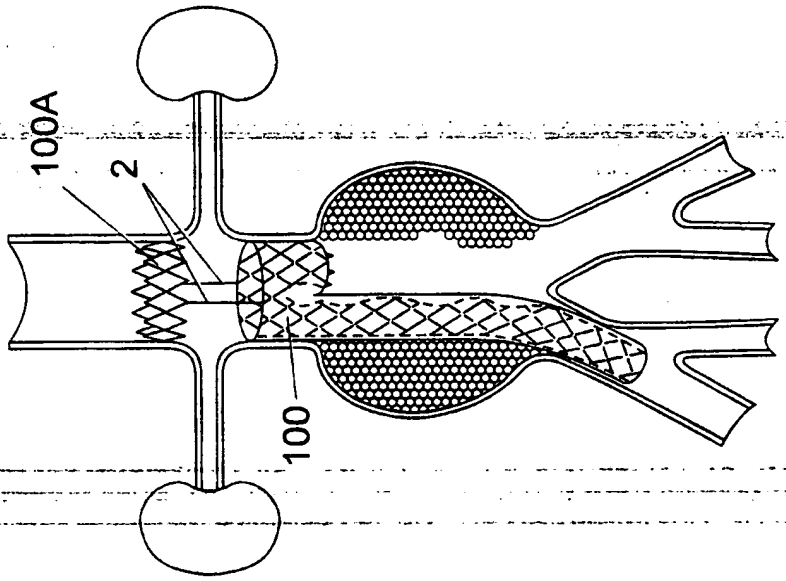


Fig. 17

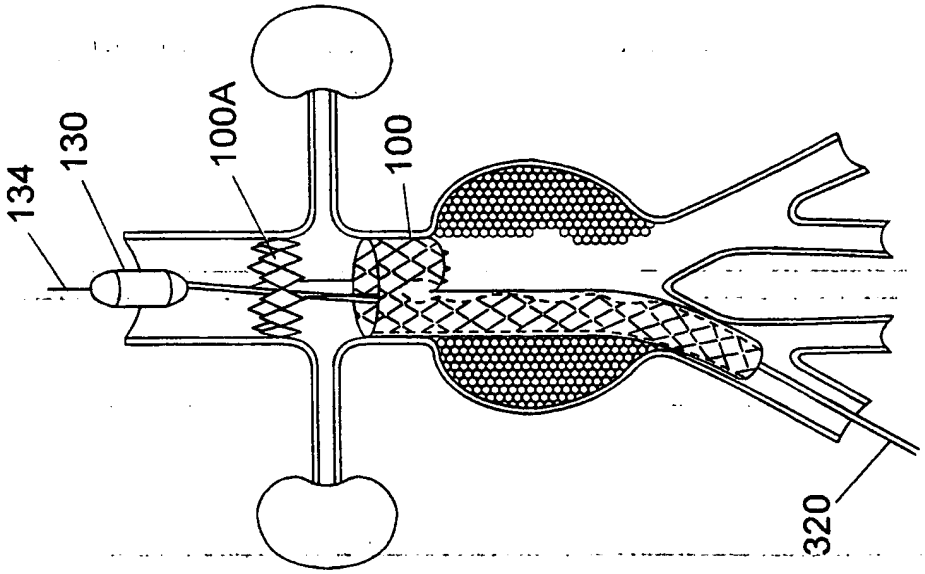


Fig. 16

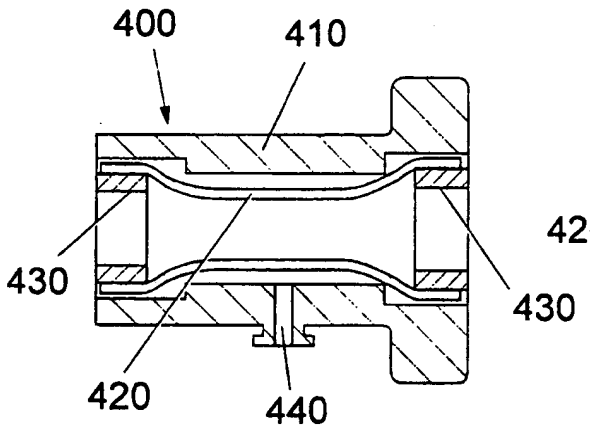


Fig. 18A

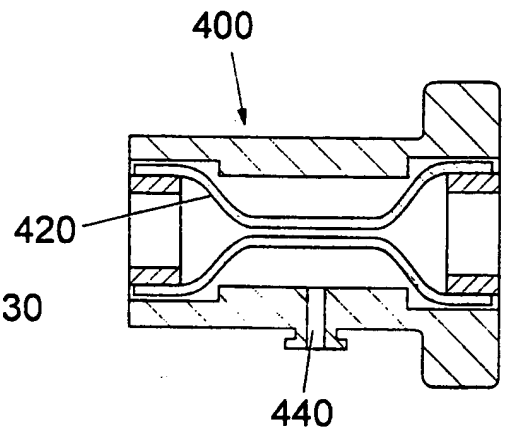


Fig. 18B

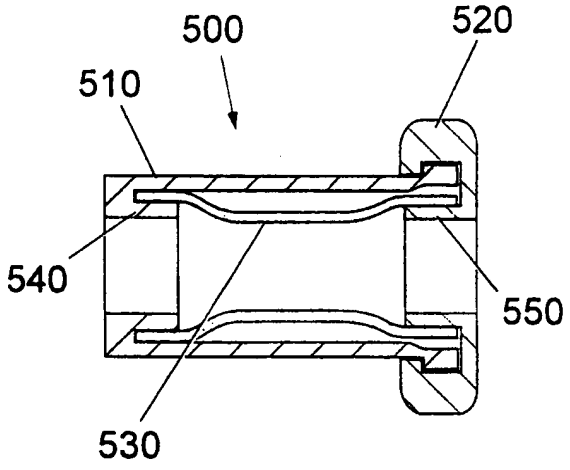


Fig. 19A

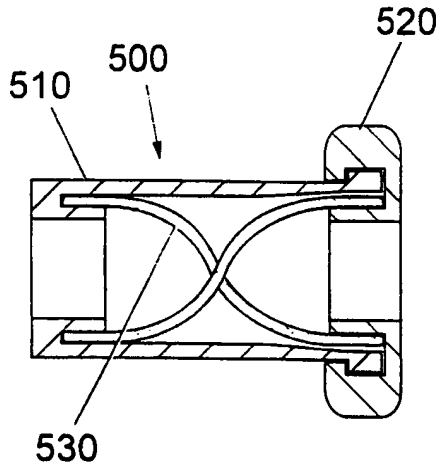


Fig. 19B

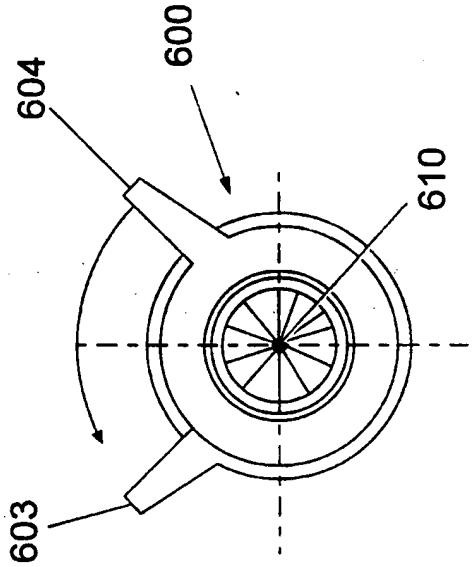


Fig. 21

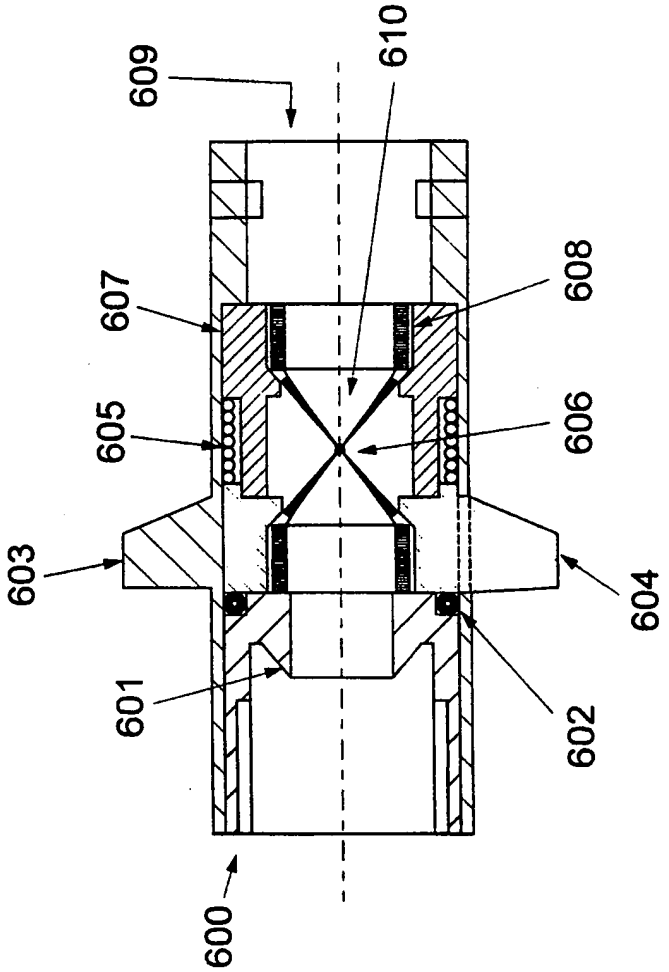


Fig. 20

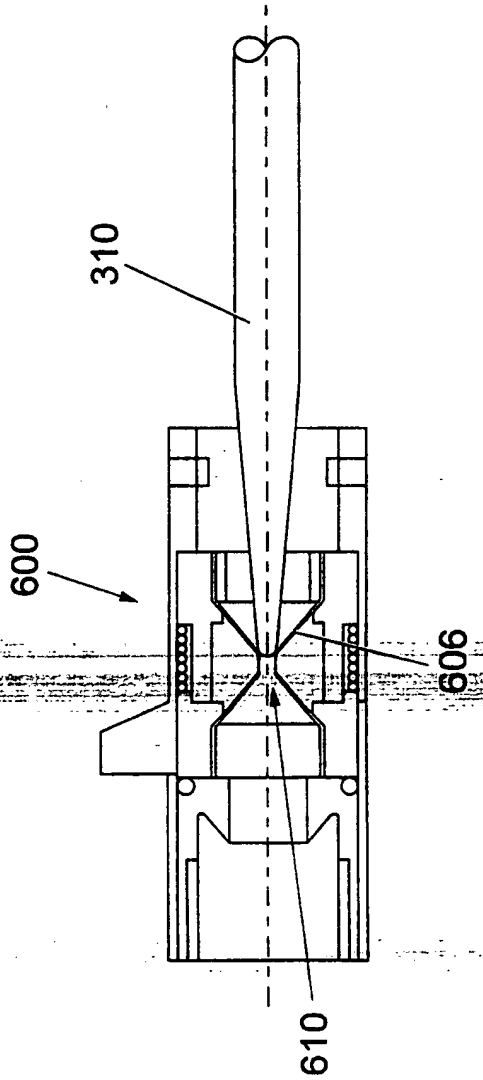


Fig. 22

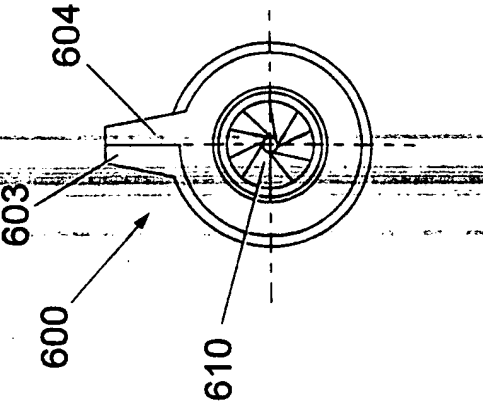


Fig. 23

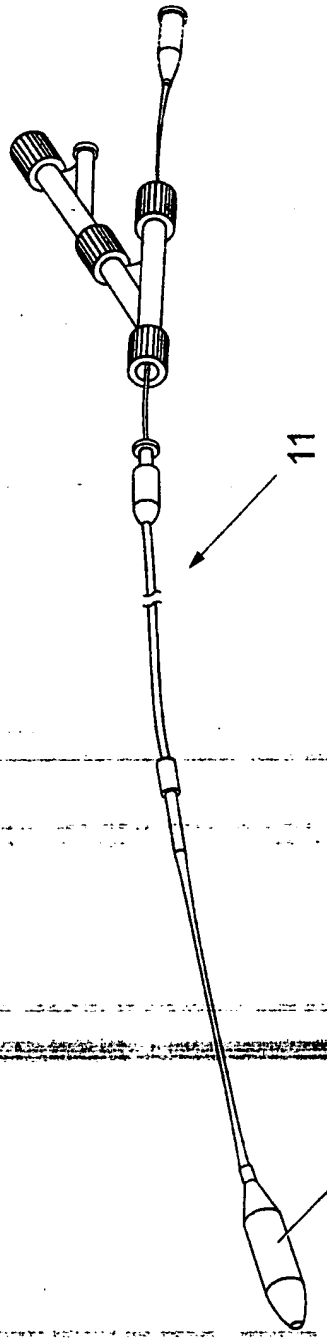


Fig. 24

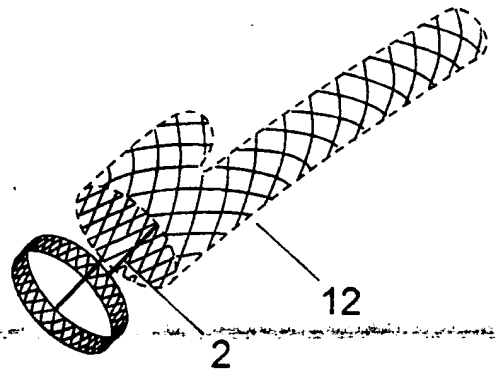


Fig. 25A

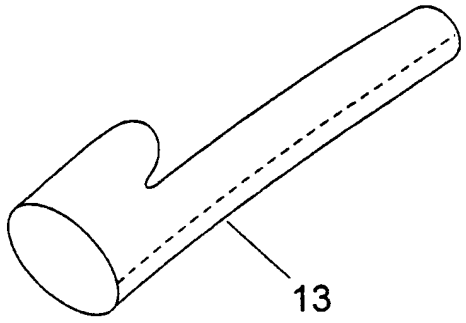


Fig. 25B

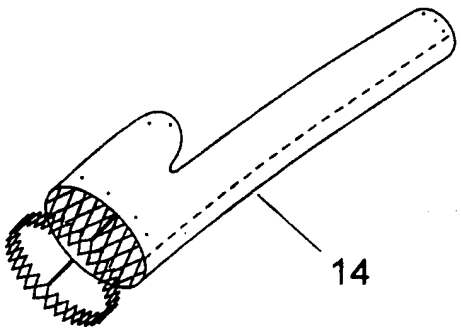


Fig. 25C

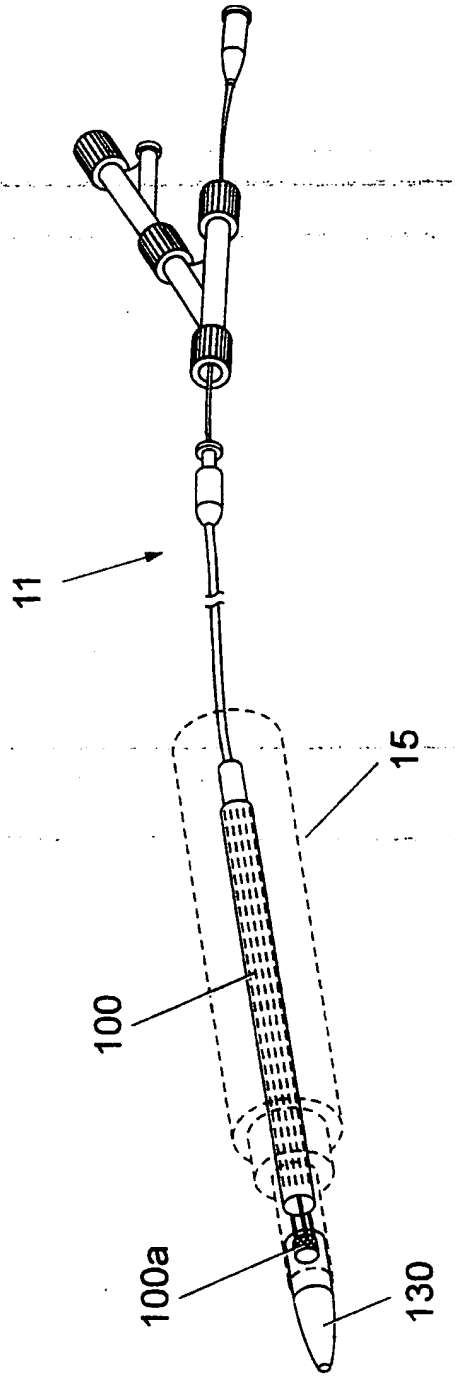


Fig. 26

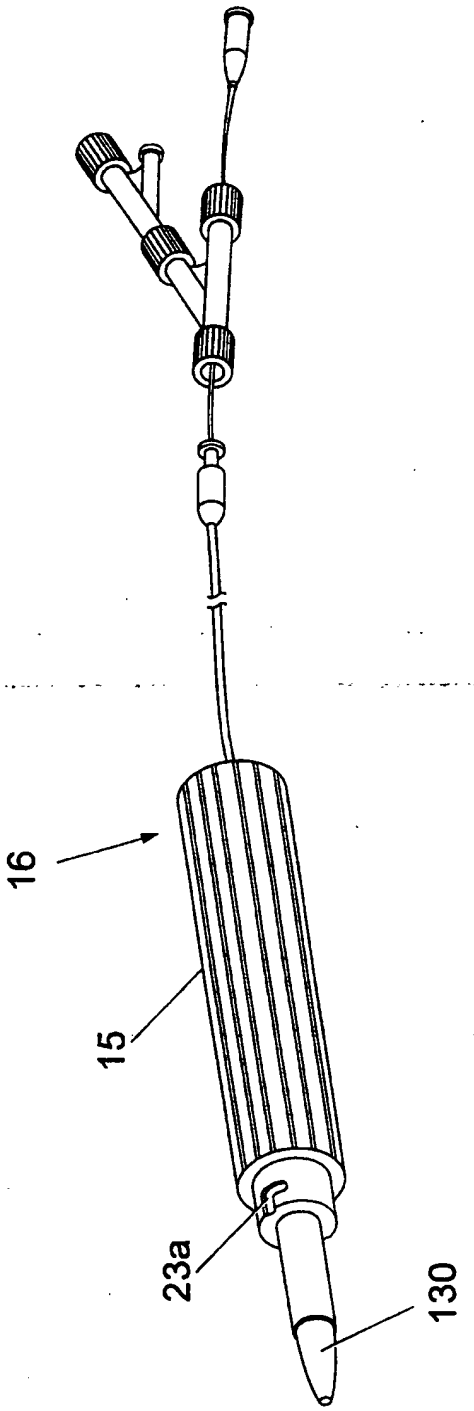


Fig. 27

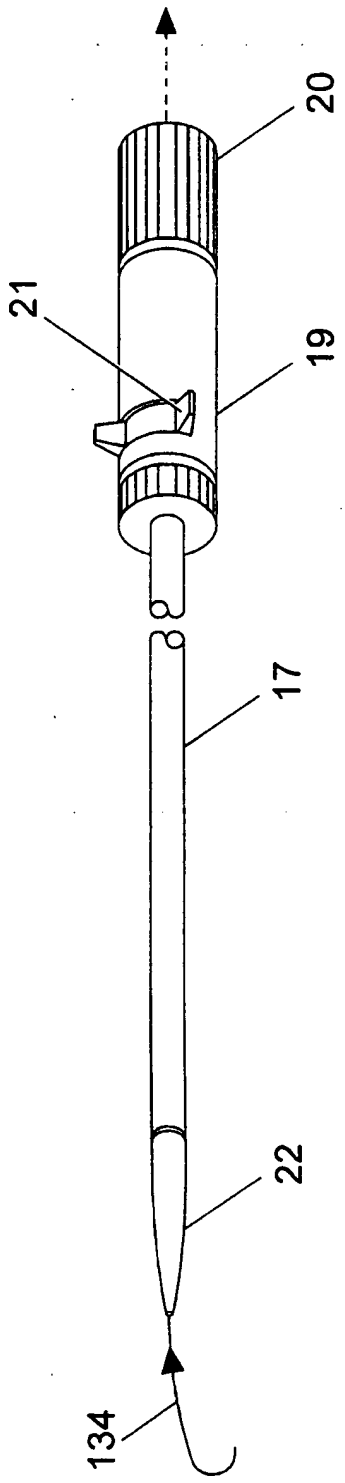


Fig. 28

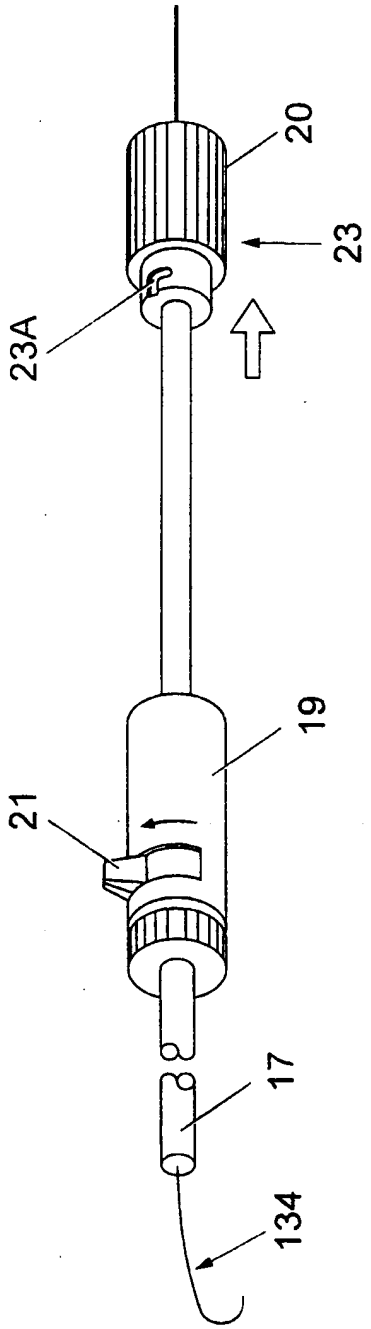


Fig. 29

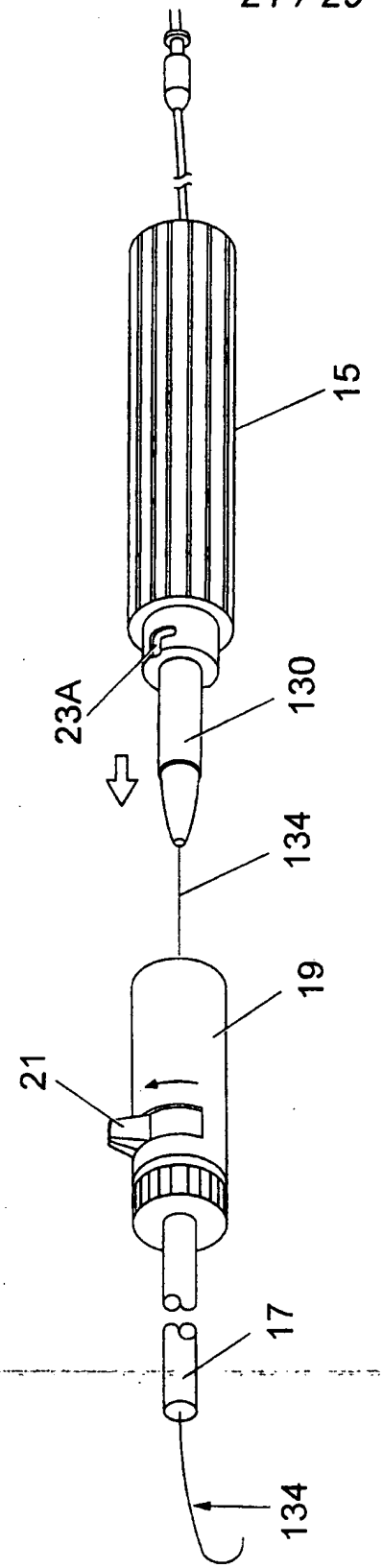


Fig. 30

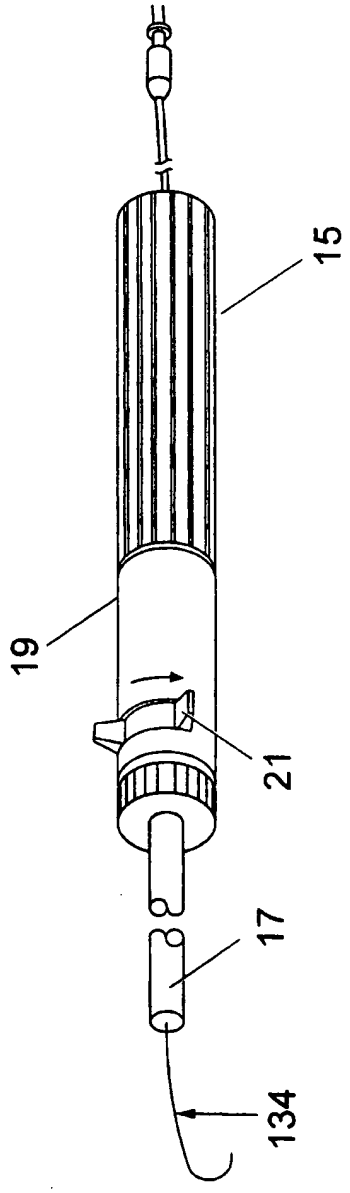


Fig. 31

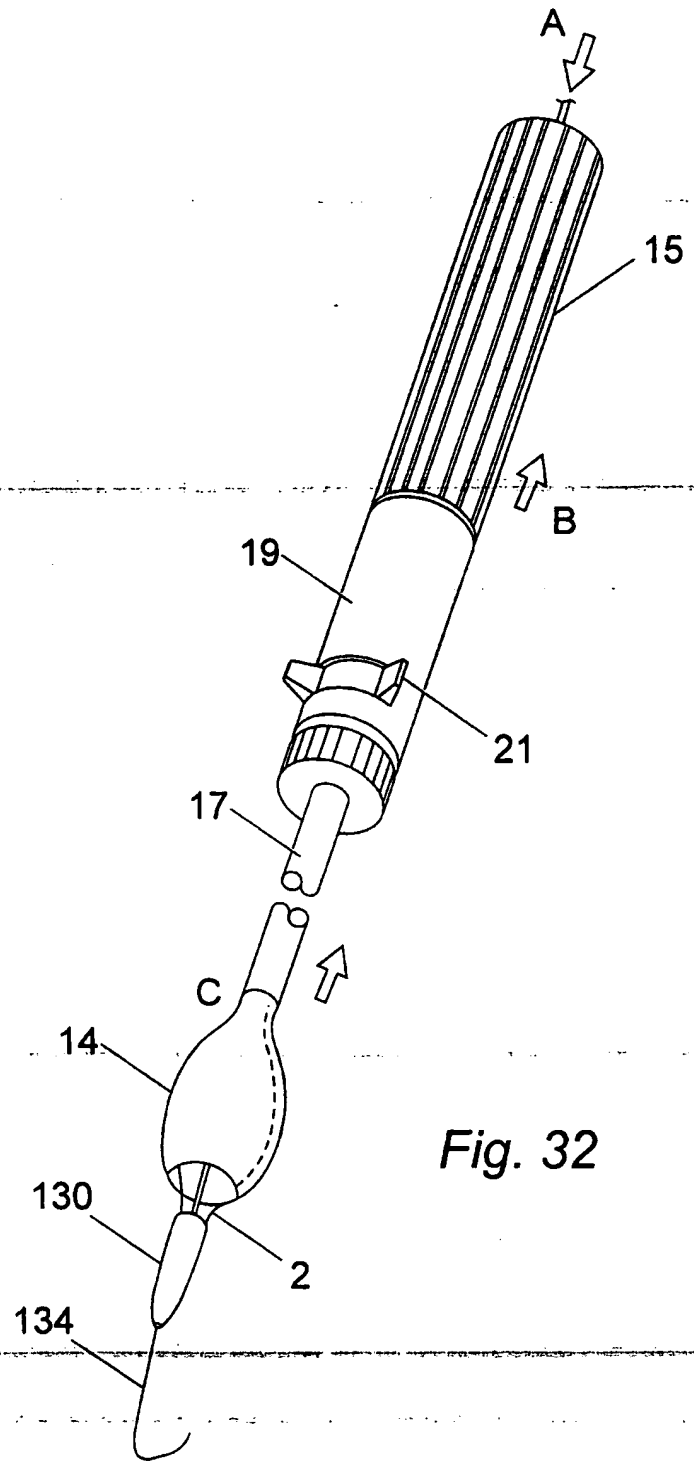


Fig. 32

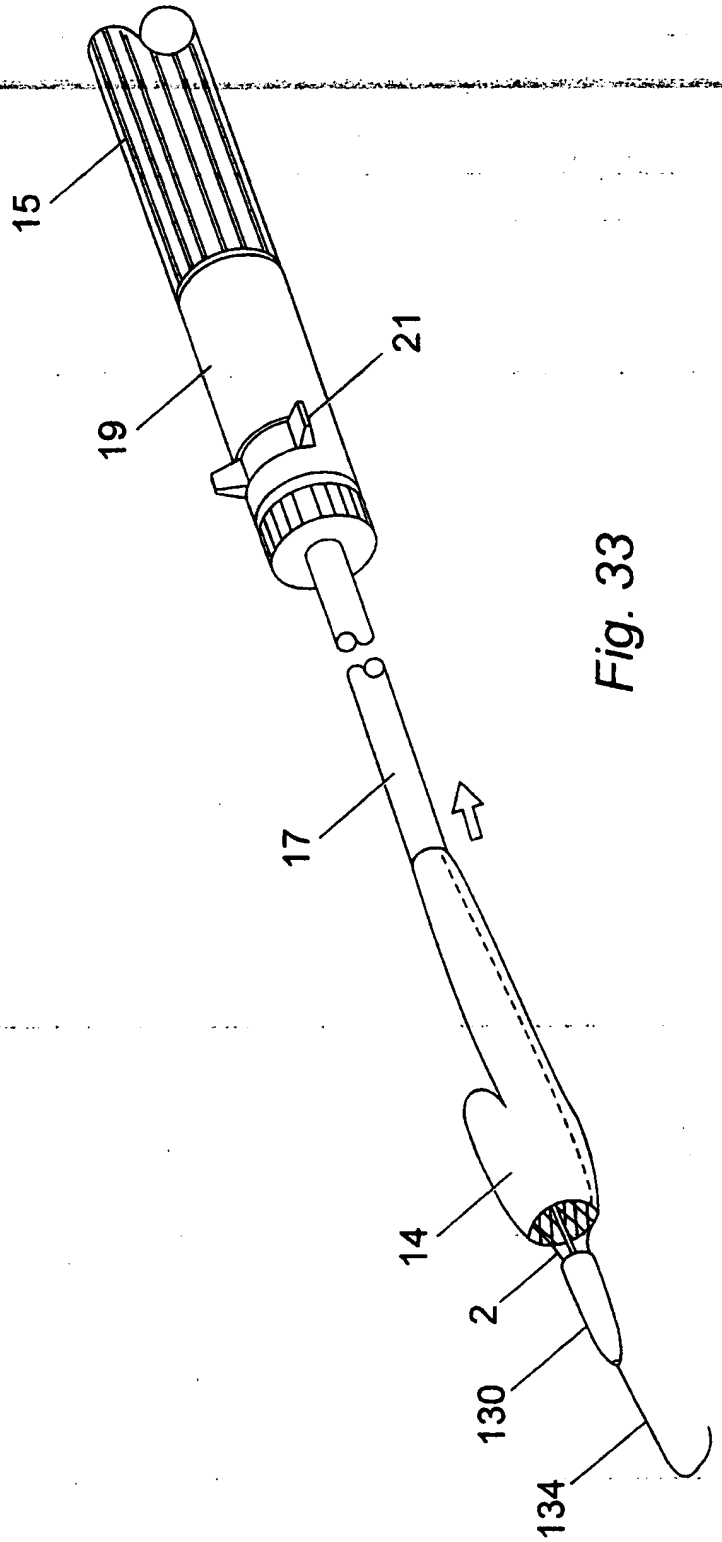


Fig. 33

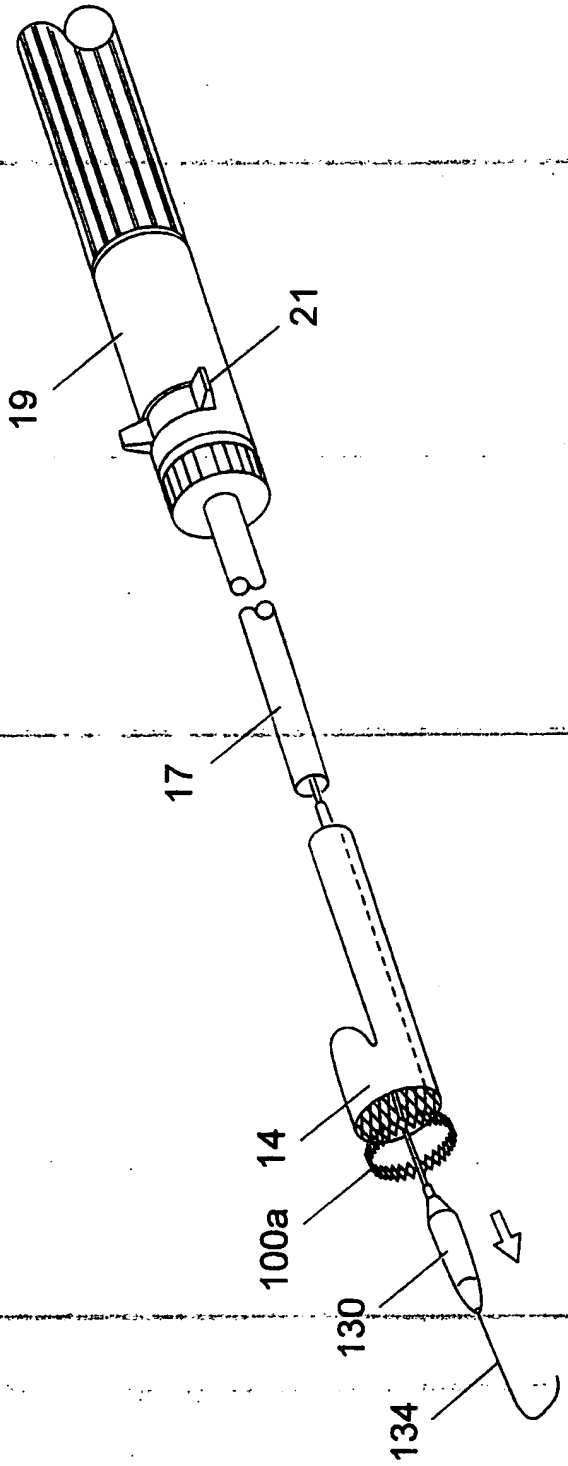


Fig. 34

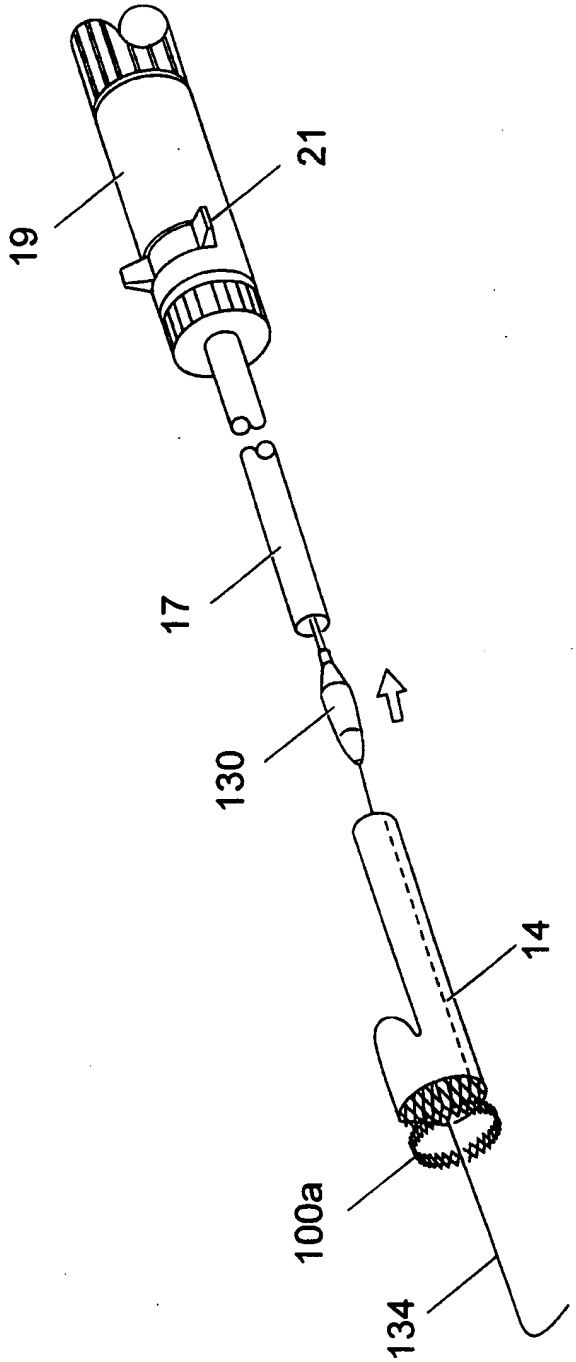


Fig. 35

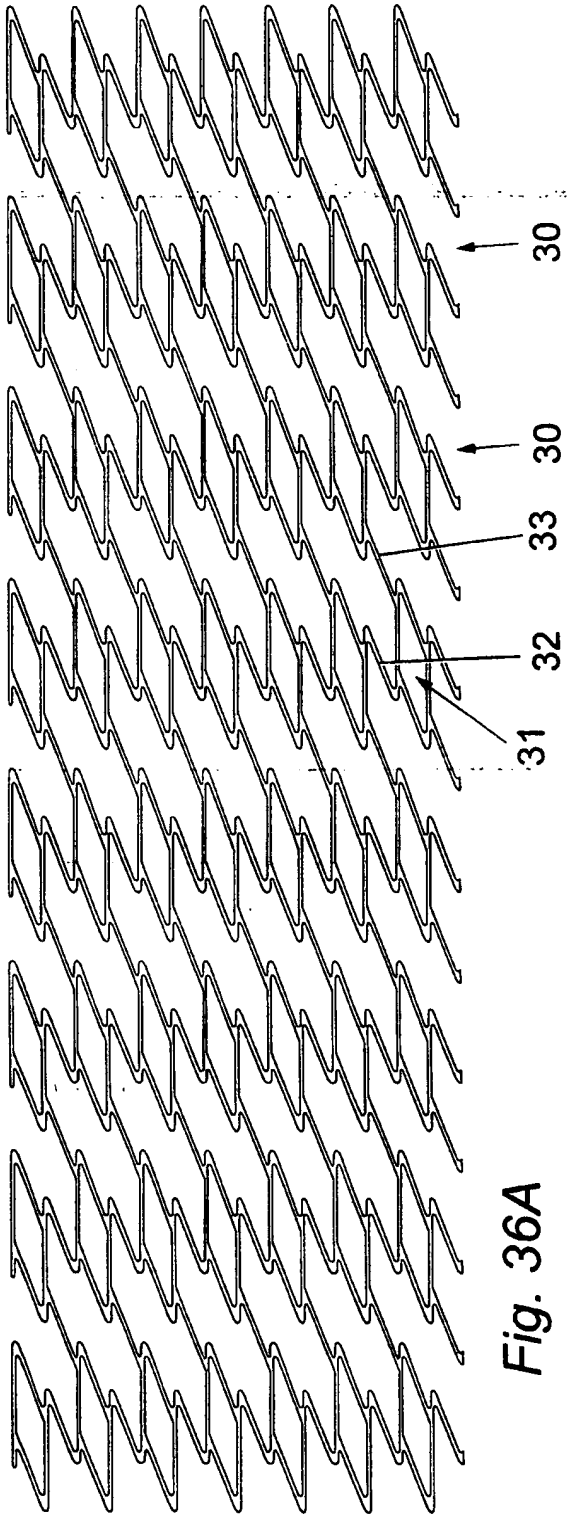


Fig. 36A

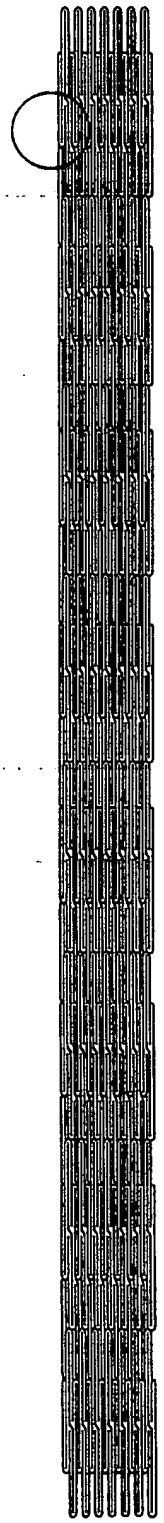


Fig. 36B

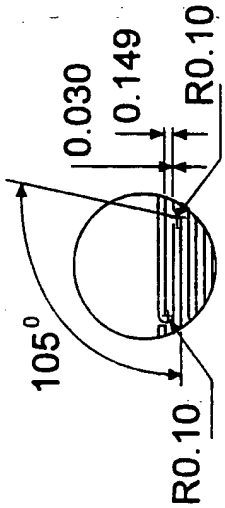


Fig. 36C

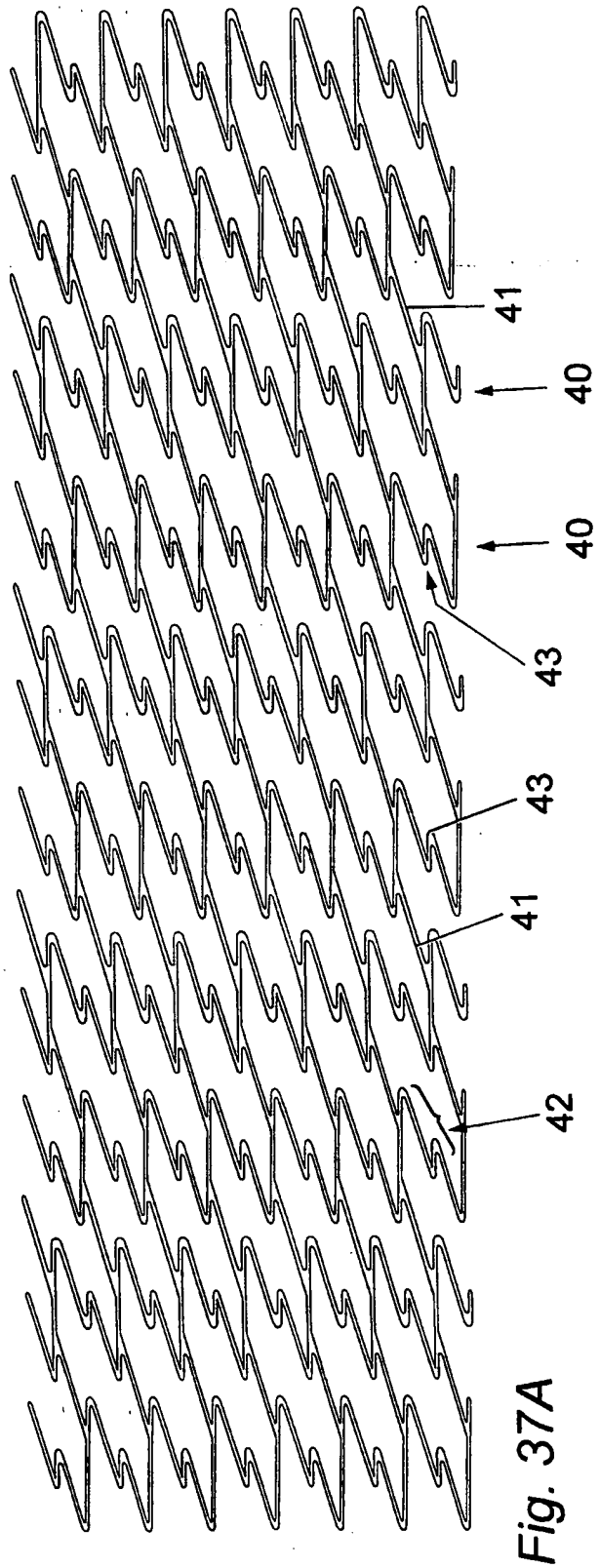


Fig. 37A

Fig. 37B

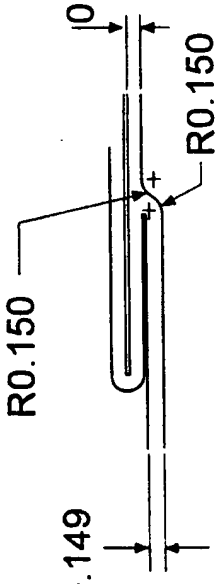


Fig. 37C

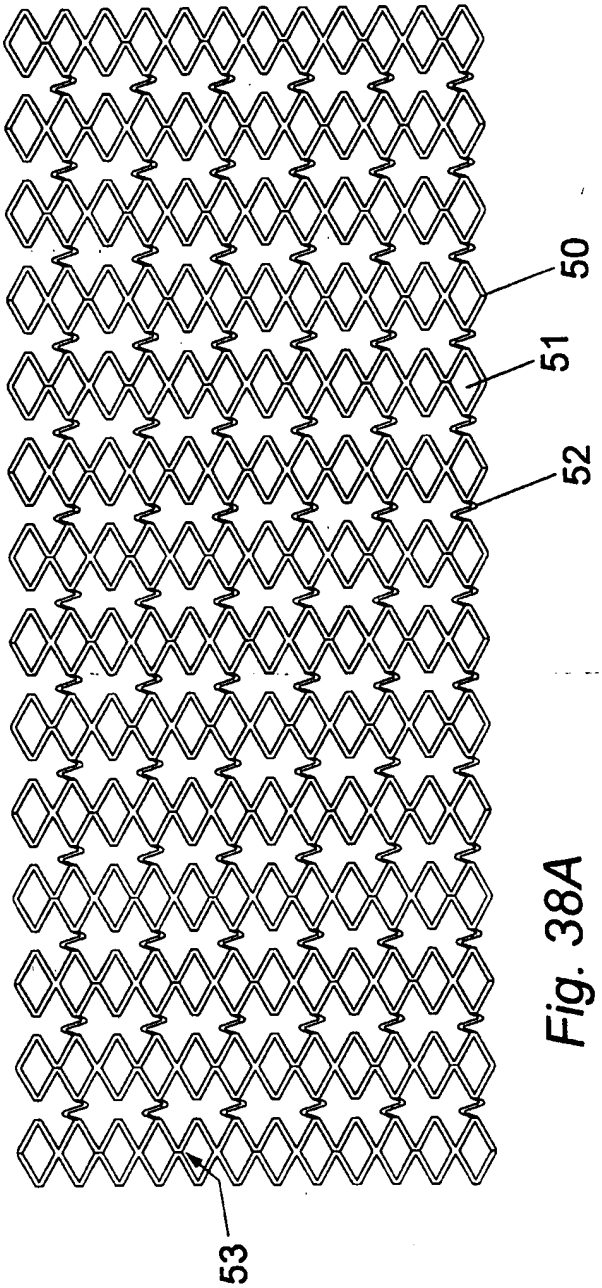


Fig. 38A

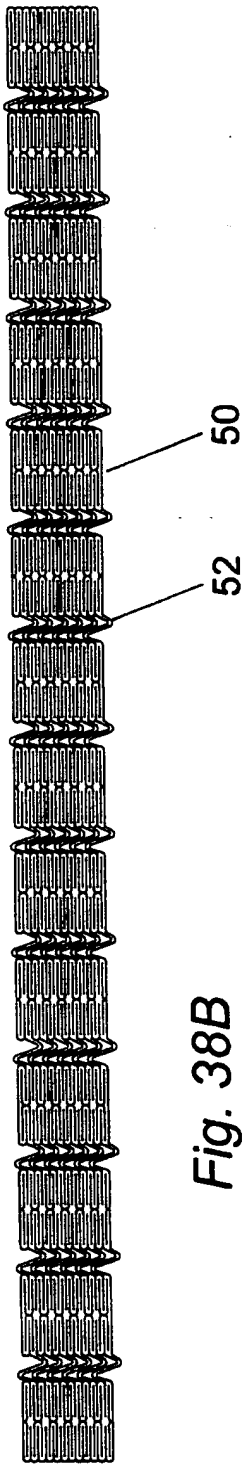


Fig. 38B

INTERNATIONAL SEARCH REPORT

Inter ...nal Application No
PCT/GB 98/00867

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61F2/06

According to International Patent Classification(IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 0 461 791 A (BARONE HECTOR D ;PARODI JUAN C (AR); PALMAZ JULIO C (US)) 18 December 1991	1
A	see column 10, line 11 - line 14; claims; figure 7	2-5,8, 14,15, 18,20,24
A	US 5 464 449 A (RYAN TIMOTHY J ET AL) 7 November 1995 see column 5, line 46 - line 55; figure 14	1,15,20
P,A	FR 2 743 293 A (DENIS JEAN MARC) 11 July 1997 see page 5, line 6 - line 11; claim 4; figure 4	1,13

-/--

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
10 July 1998	20/07/1998

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040. Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Kanal, P

2

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

Inte. ɔnal Application No
PCT/GB 98/00867

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication,where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 425 765 A (TIEFENBRUN JONATHAN ET AL) 20 June 1995 see abstract; figures	1
X	EP 0 335 341 A (EXPANDABLE GRAFTS PARTNERSHIP) 4 October 1989	8
A	see figures 7-10	11
X	US 5 449 373 A (PINCHASIK GREGORY ET AL) 12 September 1995	8
A	see figures 3A-C	9-11
A	WO 95 31155 A (STENTCO INC ;MARIN MICHAEL (US); MARIN RALPH (US)) 23 November 1995 see abstract; figures	15,20

2

INTERNATIONAL SEARCH REPORT

Information on patent family members

Inter ional Application No
PCT/GB 98/00867

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
EP 0461791 A	18-12-1991	US 5360443 A	01-11-1994
		AT 146957 T	15-01-1997
		AU 673291 B	31-10-1996
		AU 7754694 A	05-01-1995
		AU 655418 B	22-12-1994
		AU 7809291 A	12-12-1991
		CA 2043562 A	12-12-1991
		DE 69123882 D	13-02-1997
		DE 69123882 T	07-08-1997
		ES 2095293 T	16-02-1997
		JP 4231954 A	20-08-1992
		US 5578071 A	26-11-1996
		US 5571171 A	05-11-1996
		US 5522880 A	04-06-1996
		US 5578072 A	26-11-1996
		US 5693087 A	02-12-1997
		US 5571173 A	05-11-1996
		US 5643208 A	01-07-1997
		US 5591229 A	07-01-1997
		US 5683452 A	04-11-1997
US 5464449 A	07-11-1995	AU 7218794 A	06-02-1995
		EP 0707462 A	24-04-1996
		JP 8512227 T	24-12-1996
		WO 9501761 A	19-01-1995
FR 2743293 A	11-07-1997	WO 9725001 A	17-07-1997
US 5425765 A	20-06-1995	NONE	
EP 0335341 A	04-10-1989	US 5102417 A	07-04-1992
		AU 633478 B	04-02-1993
		AU 3174289 A	28-09-1989
		CA 1330186 A	14-06-1994
		GR 3003986 T	16-03-1993
		JP 1299550 A	04-12-1989
		KR 9711350 B	10-07-1997
		KR 9711351 B	10-07-1997
		KR 9711352 B	10-07-1997

INTERNATIONAL SEARCH REPORT

Information on patent family members

Inte: ›nal Application No
PCT/GB 98/00867

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 5449373 A	12-09-1995	WO 9633671 A	31-10-1996
		US 5733303 A	31-03-1998
		AU 2427995 A	18-11-1996
		DE 19581506 T	21-08-1997
		EP 0828461 A	18-03-1998
		FI 974063 A	19-12-1997
		NO 974938 A	19-12-1997
		PL 322980 A	02-03-1998
WO 9531155 A	23-11-1995	US 5456694 A	10-10-1995
		AU 2597195 A	05-12-1995
		CA 2189794 A	23-11-1995
		EP 0758871 A	26-02-1997
		JP 10500335 T	13-01-1998
		US 5697948 A	16-12-1997
		US 5569296 A	29-10-1996